



USAID
FROM THE AMERICAN PEOPLE

ACED
Agricultural Competitiveness and
Enterprise Development Project



REGULATORY IMPACT ASSESSMENT MANUAL FOR REGULATIONS WITH POTENTIAL IMPACT ON AGRICULTURE

CONDUCTED SEPTEMBER – DECEMBER 2011

**AGRICULTURAL COMPETITIVENESS AND ENTERPRISE DEVELOPMENT
PROJECT (ACED)**

JANUARY 2012

This report is made possible by the support of the American people through the United States Agency for International Development (USAID). The contents are the sole responsibility of DAI and do not necessarily reflect the views of USAID or the United States Government.

REGULATORY IMPACT ASSESSMENT MANUAL FOR REGULATIONS WITH POTENTIAL IMPACT ON AGRICULTURE

CONDUCTED SEPTEMBER - DECEMBER 2011

Program Title:	Agricultural competitiveness and Enterprise Development (ACED) Project
Sponsoring USAID Office:	USAID Ukraine Regional Contract Office
Contract Number:	AID-117-C-11-0001
Contractor:	DAI
Date of Publication:	January, 2012
Author:	DAI/BRC

The authors' views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.

CONTENTS

CONTENTS	2
ACRONYMS AND TERMS	4
INTRODUCTION	5
1 GENERAL RIA RELATED ASPECTS	7
1.1 REGULATORY IMPACT ASSESSMENT AND ITS IMPORTANCE.....	7
1.2 DEFINITION OF THE PROPORTIONALITY LEVEL IN THE ANALYSIS. PRELIMINARY AND FINAL RIAs	8
1.3 HOW TO FIND HELP AND SUPPORT	12
2 PRINCIPLES OF GOOD REGULATION	15
3 RIA PROCESS	21
4 RIA STAGES AND ELEMENTS	27
4.1 DATA COLLECTION AND CONSULTATION	28
4.2 PROBLEM DEFINITION.....	30
4.2.1 Problem analysis process.....	30
4.2.2 Problem definition when the intervention is prescribed, including in the case of harmonization with the EU legislation	33
4.2.3 Reasons for government intervention.....	34
4.3 SETTING OBJECTIVES	38
4.4 IDENTIFYING OPTIONS	40
4.4.1 Stages of identifying options	40
4.4.2 Types of alternative options	41
4.4.3 Identification of options in case of harmonization with the EU legislation	44
4.5 ASSESSING THE IMPACTS AND COMPARING OPTIONS	46
4.5.1 Decision making criteria.....	47
4.5.2 Analytical methods for analyzing the impacts and comparing options	47
4.5.3 Identifying impacts	49
4.5.4 Quantification and in-time distribution of impacts.....	55

4.5.5	Comparing and recommending options	58
4.6	IMPLEMENTATION AND MONITORING.....	61
5	RIA DOCUMENT	63
	ANNEX 1. MAIN RIA QUALITATIVE CRITERIA GROUPED INTO KEY ELEMENTS.....	67
	ANNEX 2. EXAMPLE OF NET PRESENT VALUE CALCULATION (COST-BENEFIT ANALYSIS)	74

ACRONYMS AND TERMS

RIA ¹	Regulatory Impact Analysis / Regulatory Impact Assessment
WG	Working Group for Regulating Entrepreneurial Activity
GR	Government Resolution
Law No. 235	Law on Key Principles for Regulating Entrepreneurial Activity No. 235 of 20.07.2006
GR No. 1230	Government Resolution on Approving the Methodology for Carrying out Regulatory Impact Assessment and Monitoring the Regulatory Act Efficiency
Law No. 317	Law on Regulations of Government and other Central and Local Public Administration Authorities No. 317 of 18.07.2003
Law No. 780	Law on Legislative Acts No. 780 of 27.12.2001
Law No. 160	Law on Entrepreneurial Activity Regulation through Authorization No. 160 of 22.07.2011
GR No. 1181	Government Resolution on Monitoring the Legislation Implementation Process No. 1181 of 22.12.2010
GR No. 1429	Government Resolution on Reviewing and Improving the Normative Framework Regulating Entrepreneurial Activity No. 1429 of 16.12.2008
RIA Methodology	Methodology for Carrying Regulatory Impact Assessment and Monitoring the Regulatory Act Efficiency , approved through Government Resolution No. 1230 of 24.10.2006

¹ Law No. 235 uses the term regulatory impact assessment, while Government Resolution No. 1230 - the term regulatory impact analysis. Although the terms differ a little, they mean the same thing.

INTRODUCTION

This manual was conceived as guidelines for carrying out the Regulatory Impact Assessment (RIA) for regulations with potential impact on agriculture. The manual is designed as a support to the Methodology for Carrying Regulatory Impact Assessment and Monitoring the Regulatory Act Efficiency, approved through Government Resolution (GR) No. 1230 and contains recommendations for applying good practices contributing to the development of a better quality RIA.

While developing the manual, the authors used the following approaches:

- **Good regulation principles.** Over the past years, particularly starting with the implementation of the so-called law “Guillotine I” (Law on Reviewing and Improving the Normative Framework Regulating Entrepreneurial Activity No. 424), several good regulation principles have been implemented in Moldova. The observance of these is mandatory in the process of drafting regulations. The multitude and innovative character of these principles makes it difficult for civil servants to correctly apply them. As these represent a component part of RIA and significantly contribute to the development of quality draft regulations, the authors undertook to provide necessary explanations to all these principles to allow for a better understanding of these.
- **RIA quality criteria.** While drafting the manual, the authors took into consideration the key RIA quality criteria, which were identified and formulated according to the recommendations of international specialized organizations, such as OECD, as well as in line with the best international practices, particularly with the recommendations developed by the European Commission and some EU countries with the most extended experience in conducting RIA, such as the United Kingdom. A summary of quality criteria is presented in Annex 1. Although not all the quality criteria described in this manual are expressly provided for in the RIA Methodology used in Moldova, the compliance with the latter would allow developing a better quality RIA. Moreover, the observance of these criteria would reduce the risk of RIA rejection by stakeholders in the consulting process, including the business circles, civil society, public sector, and the Working Group for Regulating the Entrepreneurial Activity. Finally, the observance of respective criteria will allow developing better quality draft regulations, which will be to the benefit of both the private sector, and the entire society.
- **Applicability.** The manual includes several useful examples which allow a better understanding of the provided recommendations, particularly of the key RIA elements, such as problem determination, identification of options and assessment of their impact. The examples are taken from agricultural area, and are particularly related to high value products.
- **Harmonization with the EU legislation.** Although it would seem that a decision has already been made in cases of transposing the EU legislation, and there is no need for an analysis any longer, RIA is particularly beneficial in such cases. The manual addresses for the first time the RIA drafting for cases of transposing the EU legislation, by providing explanations and

examples in this sense. This subject stretches through several chapters in the manual, being especially highlighted in the most relevant chapters, such as problem definition (where the government intervention is justified) and option identification (where several solutions are taken into consideration for settling the problem and accomplishing the objectives).

It is mandatory to develop RIAs for the draft regulations developed by central and local public administration authorities. Although the manual can be used by other authorities as well, taking into account the examples presented, it is designed particularly for public authorities involved in drafting or providing legal clearance of policies and regulations dealing with high value agriculture area.

Regulations which could significantly affect high value agriculture do not include only those directly regulating agricultural products, but also those with a potential impact on various components of the value chain in this area, and would include regulations on: production and import of seeds and fertilizers, cultivation of high value products; grading, calibration and packaging of products; storage of products; transportation of products; transportation means that can be used for delivering agricultural products; placement of products on the market, etc. The constraints encountered at any of the value chains of agricultural products will obviously affect the final result, which is sector competitiveness and development.

It is important to mention the fact that the Ministry of Economy initiated the RIA Methodology reviewing process. The RIA elements described in this manual are based on quality criteria suggested by international good practices; therefore they will not come into contradiction with the new version of RIA Methodology. The chapters that will be most likely affected by an eventual amendment of the RIA Manual are those related to RIA process and RIA document. Thus, the manual will have to be reviewed once the Methodology will be changed.

To date, the State Chancellery is piloting a draft Methodological Guideline for Ex-ante Assessment of the Impact of Public Policies, which could become a mandatory one during 2012. The provisions of this Guideline can be used as additional material for drafting a RIA document, because its methodology is based on a similar approach to that of RIA Methodology. The two methodologies have two significant differences: the proposed ex-ante methodology covers a broader spectrum of policies, and not only those regulating entrepreneurial activity; the ex-ante methodology is focused to a smaller extent on business regulation, and, therefore does not cover some important good regulation principles that are found in the RIA Methodology. Given the fact that both the methodology developed by the State Chancellery, and RIA Methodology are based on the good practices of ex-ante analysis, the manual does not contradict the later, but rather reconciles both methodologies and can serve as a supplement for the impact assessment in compliance with the latter. Moreover, if a decision on merging the two methodologies is taken, the given manual will not lose its relevance.

1 GENERAL RIA RELATED ASPECTS

1.1 REGULATORY IMPACT ASSESSMENT AND ITS IMPORTANCE

About RIA

Pursuant to Law No. 235, Law No. 317, Law No. 780, and GR No. 1230, regulatory impact assessment represents an argumentation based on cost/benefit estimation of the need for adopting a regulation and analysis of its impact on entrepreneurial activity, including insurance of the observance of rights and interests of entrepreneurs and the state, as well as of the regulation compliance with the goals of regulatory policy and good regulation principles provided for in the above mentioned laws. The regulatory impact assessment act is an integral part of the information note to a draft regulation.

Both Moldova and other countries use different terms attributed to a similar process, and namely: Regulatory Impact Analysis (RIA), Regulatory Impact Assessment (RIA), Policy Impact Analysis/Assessment (PIA), Ex-ante Policy Impact Analysis or simply Impact Analysis (IA). RIA definition also differs a little in different sources, but in essence, all of them are based on the same logic and mission. The definitions of RIA from the Ex-ante Guidelines and of RIA from the European Commission Impact Assessment Guidelines are presented below:

- According to the draft Methodological Guideline for Ex-Ante Public Policy Impact Analysis developed by the State Chancellery: ex-ante analysis is the first stage of the decision making process – public policy development. This stage presumes identification of the problem, objective, and eventual options for settling the problem and reaching the objective and analysis of the effects and consequences of these options before making respective decision. In other words, ex-ante analysis is nothing but a number of logic steps to be followed in the public policy development process which can also be materialized in regulations.
- According to the Impact Assessment Guidelines developed by the European Commission in 2009: Impact assessment is a set of logic steps to be followed upon preparation of policy proposals. This is a process in which evidence/information is prepared for the policy decision makers in terms of advantages and disadvantages of possible policy options through evaluating the potential impact of the latter. The results of this process are systematized and presented in an Impact Assessment Report.

Pursuant to Law No. 235, RIA became mandatory on 1 January 2008. During the last four years, over 380 RIAs were developed and presented to the Working Group for Regulating Entrepreneurial Activity for review, of which over 100 related to agriculture area.

RIA Importance

The decisions on public policies, including on regulations, should be based on a sound analysis

of facts and data available in order to be able to select the most favorable solution for solving a public problem. Therefore, RIA is a crucial process in drafting quality public decisions.

RIA provides a number of advantages, in particular:

- helps develop better public policies and regulations;
- facilitates the approval of better informed decisions in the process of developing the regulatory framework;
- insures taking into consideration the contribution of a broader range of external stakeholders, in compliance with the provisions of the legislation on transparency in the decision making process;
- helps insuring coherence of the proposed actions with the government policies, regulatory framework, and principles of good regulation;
- improves the quality of policy proposals through cost/benefit analysis of different policy alternatives and helps maintaining the government interventions as simple and effective as possible;
- helps explain why the proposed action is necessary and adequate;
- helps negotiate international agreements and harmonization process, including with the EU legislation, as well as in assessing the effects of the latter, for developing actions for preventing adverse effects, negotiating the technical assistance, transition period, derogations, institutional arrangements, and enforcement mechanisms for a more favorable implementation of the provisions. More examples in this sense are presented throughout the manual, within the relevant RIA elements.

1.2 DEFINITION OF THE PROPORTIONALITY LEVEL IN THE ANALYSIS. PRELIMINARY AND FINAL RIAs

RIA should provide the decision makers with solid information/evidence on the need for government intervention, as well as on both positive and negative impacts of the proposed interventions so as to support approving an informed decision. However, one should avoid wasting the efforts for carrying out an analysis if the latter doesn't bring sufficient added value evidence/information for a better quality decision. The principle of proportionality is applied in RIA for the purpose of insuring a more reasonable allocation of effort and resources, which refers to the detailing level of analysis.

The principle of proportionality relates to both thoroughness, coverage of the analysis and detailing of RIA in general and to the detailing of each separate RIA element, such as data collection and consultation of stakeholders; problem definition; setting of objectives; identification of options; analysis of impacts and planning of implementation and monitoring actions.

The RIA authors and working groups established for the purpose of RIA development should take into consideration the adequate level of analysis and evaluation in the incipient phase of the process, preferably at the stage of RIA planning, but at the same time keeping in mind that the situation can change and a more rigorous analysis may be required with the advancement of RIA process.

Examples of criteria for estimating the required level of analysis are provided in the box below:

According to the EU Impact Assessment Guidelines: While defining the adequate level of analysis, the following questions should be answered:

- How significant are the possible impacts of the proposed options?
- How important is the proposed initiative from the political point of view?

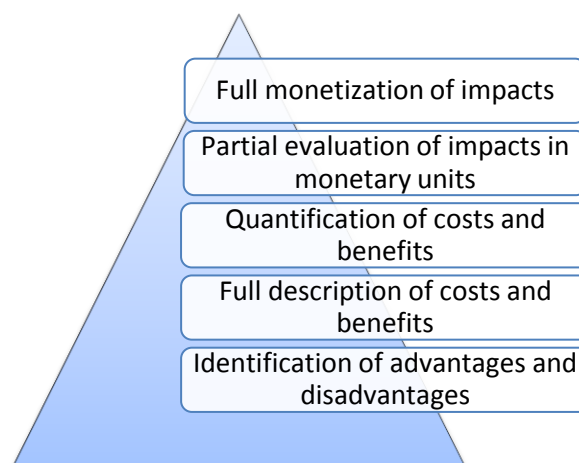
According to the British RIA Guidelines: The key factors for determining the level of analysis are:

- The level of interest and sensitivity towards the proposed initiative.
- How new, disputable, and irreversible the proposal is.
- The policy development stage.
- The size, duration, and distribution of potential impacts.
- The uncertainty degree of potential impacts.
- Data already available and resources required for additional data collection.
- The time available for policy development.

In addition, the manager of the institution that is preparing RIA document can request a more rigorous level of analysis in order to respond to potential questions that the persons consulted and those providing legal review to RIA documents may ask.

Finally, the detailing level of analysis will depend on the consulted stakeholders, including public authorities (for e.g., the Ministry of Finance can request a more rigorous analysis of the potential budget impacts), and private sector.

With regard to impact assessment, the detail level of analysis can be represented according to the following scheme:



Most of the RIAs do not require a very rigorous analysis and could be limited to the identification of advantages and disadvantages, with partial quantification of impacts. For more important issues, a quantification of key impacts in monetary units would be required.

According to RIA Methodology in Moldova, prior to the development of a regulation, the public administration authority would develop a preliminary regulatory impact assessment which is sent for legal review to the Working Group for Regulating the Entrepreneurial activity. The Working Group issues a decision through which the latter rejects the preliminary RIA, or accepts the preliminary RIA, or requests a broader analysis, in form of a final RIA, which will be presented together with the draft regulations.

The difference between the preliminary RIA and final RIA is presented in the Table below. The two RIA forms are compared by key components identified on basis of Moldovan RIA Methodology and best international practices.

RIA component	Preliminary RIA	Final RIA
Problem definition	<p>Preliminary RIA defines the problem that is to be settled and establishes the potential results of the government regulation. Problem definition must contain the following elements:</p> <ul style="list-style-type: none"> • legal component, which would indicate the way in which the problem is related to a public administration authority, for the government intervention and the current legal framework on the addressed area; • analytical element, which would explain the reason for problem emergency and estimate its dimensions; • estimation of possible consequences in cases when no action is taken; • setting the goals of government actions. 	The same as in the preliminary RIA
Setting objectives	There is a mention in the section on problem definitions that the RIA authors set the goals of government actions.	The same as in the preliminary RIA
Identifying options	To identify at least two options, one of which would be a "do nothing" option	The number of options is not indicated, therefore there are at least two options, like in the preliminary RIA
Impact analysis	To identify the major potential impacts of government intervention in quantitative and qualitative terms. This impacts will be grouped as	<p>To identify the potential impacts, which include:</p> <ul style="list-style-type: none"> • benefits (all the major positive impacts, including on public

	<p>follows:</p> <ul style="list-style-type: none"> • negative impacts or the costs of government intervention; • positive impacts or the benefits of government intervention. <p>In addition to costs and benefits which are also analyzed in the case of final RIA, the following must be analyzed in:</p> <ul style="list-style-type: none"> • major uncertainties referring to potential impacts of government intervention. 	<p>health, national security and environment protection);</p> <ul style="list-style-type: none"> • costs (all the major negative impacts, including social and economic costs). <p>In addition to the costs and benefits which are also analyzed in the preliminary RIA, the following must be analyzed:</p> <ul style="list-style-type: none"> • impacts on small and medium enterprises (any negative or positive effects on the foundation and operation of small and medium enterprises); • major distribution problems.
Comparing the options	Options are compared in table format, based on advantages and disadvantages.	Unlike the preliminary RIA, options are compared in table format, based on benefits and costs, impacts on small and medium enterprises, distribution problems and uncertainty, with the final goal of determining the net benefits within the table.
Consultations	A description of the consultations strategy is required in the preliminary RIA document. The latter identifies the key stakeholders that can be affected by the regulation and explains the way in which the process of consultation and communication with respective stakeholders will take place. Such analysis establishes the major data needs and how consultations will help meeting respective needs.	The Methodology does not provide for a separate section on consultations. However, the chapter on RIA development process stipulates that the final RIA, together with the draft regulation is reviewed by interested authorities and institutions, and by the WG in compliance with the legislation. The draft regulation and the final assessment are posted on the web page of the public administration authority for public consultations.
Implementation and monitoring	These sections are not planned in the preliminary RIA	The final regulatory impact assessment proposes an implementation strategy and estimates the financial cost of implementation; current capacities of the public administration authorities responsible for the implementation of the regulatory act and of other actions; in addition to implementation related aspects, the final RIA must

		identify specific and measurable indicators for monitoring the performance of the act in direct relation with the goals identified by government intervention. The enforcement date of a proposed draft is also justified through final RIA.
--	--	--

As mentioned in the introductory part of the manual, the Ministry of Economy is in process of reviewing the RIA methodology, therefore the preliminary and final RIA components could change.

1.3 HOW TO FIND HELP AND SUPPORT

There are several interested parties in the RIA process that could contribute to the quality of assessment. The support for RIA development can be obtained from the following institutions and persons:

Working Group for Regulating Entrepreneurial Activity (WG)

The WG has the role of evaluating the quality of RIA and of draft regulations through the RIA Methodology and principles of good regulation. The WG meetings are open, and are usually held every Wednesday, at 14:00, in office 246 of the Ministry of Economy and can be watched and commented on-line on the web site www.privesc.eu. Given that the WG is assisted by RIA Secretariat, the latter acts as the WG contact point.

RIA Secretariat

The Secretariat supports the WG in carrying out evaluation of RIA and of draft regulations delivered for review. The Secretariat includes six (6) experts specialized in specific areas and public authorities (for example, one expert from within the Secretariat is designated to review all the regulations on agriculture and liaison with Ministry of Agriculture and Food Industry). The Secretariat sits in the premise of the Ministry of Economy, which provides logistic support to the latter. The Secretariat can be contacted at the following phone numbers:

- 25-05-33 – WG Secretary, and
- 25-05-52 – Experts Group of RIA Secretariat.
- Email: secretariat.eir@gmail.com

Ministry of Economy

Pursuant to item 4 of GR No. 1230, the Ministry of Economy monitors the efficiency of Regulatory Impact Assessment and provides methodological assistance, as required, to ministries and other central administrative authorities in the process of carrying out regulatory impact assessment.

Academy of Public Administration

Courses on RIA or Ex-ante policy impact analysis are organized within the Academy for Public Administration under the President of the Republic of Moldova. Both courses are useful in building and improving the capacity for RIA development.

Persons from within the public institutions that benefited from training and developed RIAs

To date, several persons from practically all public authorities have participated in training courses on RIA and Ex-ante Analysis. You can request the list of these persons from the Academy for Public administration or directly from the person or unit responsible for RIA from within your authority.

Examples of RIA developed in Moldova

During the last four years, there were developed and submitted for review to the WG over 380 RIAs, 100 of which were from agricultural sector.

There is no unique data base on RIAs in Moldova. Therefore, if you want to consult some RIAs, you can find them on the web page of the author institution or request examples from the RIA Secretariat. A larger collection of RIAs developed in Moldova is posted on the webpage of the Ministry of Economy: <http://www.mec.gov.md/sector/241/952>

Experience and good practices from other countries

Guidelines on RIA

Below are presented the links to RIA methodologies from the European Commission and the United Kingdom, which is the most advanced EU country with regard to RIA. There you can find new analytical techniques or new approaches to applying the existing RIA techniques.

- EU Guidelines for Impact Analysis:
http://ec.europa.eu/governance/impact/docs/key_docs/iag_2009_en.pdf
- Annex to the EU Guidelines:
http://ec.europa.eu/governance/impact/docs/key_docs/iag_2009_annex_en.pdf
- United Kingdom's RIA Guidelines:
<http://www.berr.gov.uk/whatwedo/bre/policy/scrutinising-new-regulations/preparing-impact-assessments/toolkit/page44237.html>
- Additional material to the UK RIA Guidelines, particularly useful for impact assessment and quantification (UK Green Book):
http://www.hm-treasury.gov.uk/data_greenbook_index.htm

The list and texts of RIAs developed by the European Commission:

The European Commission has a RIA database developed for the European legislation since 2003. RIAs are grouped by area and drafting year. The data base can be found at the following link:

http://ec.europa.eu/governance/impact/ia_carried_out/ia_carried_out_en.htm

This database is useful particularly in the context of bringing Moldovan legislation in line with the EU legislation, because the reasons/problems lying on the basis of developing the EU legislation can be better understood through these RIAs, and it can help in assessing impacts of implementing that legislation in Moldova.

The list and texts of the Impact Analyses developed in the UK: RIAs can be found by key words on the following links:

- RIA Library of the United Kingdom: <http://www.ialibrary.berr.gov.uk>
- RIA Archive of the United Kingdom Department for Environment, Food Products, and Rural Affairs (DEFRA). Here, you will find stored several RIAs on agriculture as well: <http://archive.defra.gov.uk/corporate/policy/regulat/ia/>

Technical regulations and norms on agriculture

The Catalogue of technical regulations and norms on agriculture can be found on the webpage of the National Institute for Standardization and Metrology:
http://www.standard.md/standard_search.php?l=ro

2 PRINCIPLES OF GOOD REGULATION

Law No. 235 establishes the key principles for regulating entrepreneurial activity. The implementation and observance of these principles help develop a favorable legal framework for the business environment and investment climate for social and economic development, which is goal of Law No. 235. These principles constitute important starting points based on which the entrepreneurial activity is regulated. From the moment of initiating the RIA drafting, and subsequently the development of the draft regulation, the authors must take into account these principles. Also, while developing a draft regulation, it is necessary to observe the provisions of other laws, such as Law No. 780, Law No. 317, and Law No. 160. However, given the fact that RIA development is required only in case of a draft regulation (normative act regulating entrepreneurial activity), we will mainly consider the principles provided for in Law No. 235.

Regulation of entrepreneurial activity

It is very important to establish from the very start if the expected government intervention fits in the regulatory process of entrepreneurial activity. Only in such case it would be mandatory to initiate a RIA.

Pursuant to article 3 of Law No. 235, the regulation of entrepreneurial activity means:

- setting the rights, obligations, requirements, and prohibitions for entrepreneurs throughout their entire activity (from business initiation to liquidation), and
- regulating relationships between the public administration authorities, other institutions authorized with regulatory and control functions and the entrepreneur.

It is worth remarking that an entrepreneurial activity regulation is considered to be the case when at least one of the above listed points is found in the provisions of a draft regulation. Thus, in technical terms, the regulation on entrepreneurial activity implies not only establishment of some rights, obligations or rules for direct activity of an entrepreneur, but also includes the regulation of the quality of services and products produced by the latter, or the legal regime of goods (resources) used by the entrepreneur. Imposing a conduct to the government body (which fact will implicitly reflect on the entrepreneur's activity that the given government body interacts with) also implies regulating entrepreneurial activity. In such cases, while developing the regulation and drafting a RIA, it is necessary to observe and take account of the key principles for regulating the entrepreneurial activity provided for in Law No. 235, and, as the case may be, in Law No. 160, Law No. 161, and Law No. 451. These principles have the same degree of importance, regardless of the sequence of their reflecting in next sections. They are interdependent with each other. The infringement of any of these would cause prejudices to other principles for regulating the entrepreneurial activity, to the business environment, and the society, in general.

Principle of predictability of the entrepreneurial activity regulation

Pursuant to Law No. 235, this principle is based on two essential provisions, namely:

- entrepreneurial activity is regulated through laws, government resolutions/ordinances and other regulations of public administration authorities;
- the laws establish for each separate case the regulatory limits for government and/or for public administration authorities.

Although Law No. 235 provides that different authorities have duties of regulating entrepreneurial activity, the above provisions, combined with other legal provisions, give priority to the regulation of entrepreneurial activity through Law. The Law offers the highest degree of predicting a regulation. First, the procedure for examining a draft law is more complex, ensuring complementary possibilities for participation of different social groups, including the participation of government opposition. Second, the procedure for amending a law is also more complex compared to the procedure for amending other regulations, which provides a higher degree of predicting regulations for the society. An exception from the regulation through law can be made only through establishing expressly in the law a specific area which shall be regulated by Government or a public administration authority. Thus, any draft regulation must contain a clause indicating a law provision which would establish a specific area to be regulated by respective authorities. It is expressly stipulated that the regulations of these authorities can not be invoked in case when these do not comply with the provisions of Law No. 235.

Principle of cost predictability

Law No. 235 expressly stipulates that payments for services provided and acts issued to entrepreneurs by public administration authorities and other institutions with regulatory and control functions shall be established through laws, by indicating the service, the act, and the amount to be paid for such services/acts provided/issued. Thus, it is stipulated that respective payments shall be established exclusively through law. We should highlight the fact that the laws cannot set regulatory limits in respective area for other authorities. However, it is necessary to add here that: the law should establish payments and their amount for mandatory services and acts, while for optional services and acts, the law can provide for setting the payments through other regulations (secondary legislation).

Principle of material and procedural regulation of a business initiation, operation, and liquidation

According to this principle, it is established that the following shall be set through laws:

- material norms for business initiation, operation and liquidation;
- procedural norms for business initiation, operation, and liquidation;
- material and procedural norms for carrying out control over business.

Thus, we should note that the provisions of Law No. 235 cover practically the entire spectrum for regulating entrepreneurial activity. The given provisions confirm those stated with regard to the predictability principle described above, which gives priority to the law in regulating entrepreneurial activity. Material norms mean standards through which requirements are established for entrepreneurs, employees of the latter, obtaining of some permits for premises, transport, products, etc. Procedural norms should be interpreted as norms establishing terms for carrying out some activities by entrepreneurs or authorities, specific actions of those, etc. It is

important to draw the attention to the regulation of state control over the entrepreneurial activity. Respective norms would be established in laws. In continuation, we will present some information referring to authorization of entrepreneurial activity, and other information which will also demonstrate the need for regulating the entrepreneurial activity only through law. We will highlight that the regulatory limits for other authorities that must be set through laws are very restricted. For example, the laws can establish for regulation through regulations (secondary legislation) of areas related to optional services for entrepreneurs, sampling methods, methods for laboratory analysis of samples. For these reasons, it is necessary to carry out consultations with RIA Secretariat before the initiation of a draft regulation on entrepreneurial activity.

Principle of transparency in the decision making process

Law No. 235 stipulates that public administration authorities shall inform about draft regulations and insure transparency in their decision making activity by involving the private sector, civil society and physical persons in the drafting of regulations in the decision making process.

In this context, it is worth mentioning the Law on Transparency in the Decision Making Process No. 239 of 13.11.2008. This law stipulates obligations for the public authorities to insure transparency in the decision making process. The law provides for a broad range of opportunities for civil society representatives, including for entrepreneurs and their associations, to be involved in the decision making process and influence the approval of decisions.

Principle of regulation transparency

Pursuant to Law No. 235, public administration authorities shall insure transparency of a regulation through free access to regulations and through publishing the latter in compliance with the legislation.

We would also mention the Regulation on the Procedures for Insuring Transparency in the Process of Drafting and Approving Decisions, approved through Government Resolution No. 96 of 16.02.2010 on Actions for the Implementation of the Law on Transparency in the Decision Making Process No. 239 of 13.11.2008. The Regulation sets requirements and detailed procedures for insuring transparency of the decision making process by public authorities.

It is also necessary to mention the Regulation on the Procedure of Publishing Information on the Official Web Pages of Public Administration Authorities on the internet, approved through Government Resolution No. 668 of 19.06.2006. This Regulation expressly provides for the obligation to publish the information on transparency in the decision making process, which also includes announcements about initiating the drafting of decisions; announcements about the organization of public consultations; draft decisions developed and related materials; public consultation results (minutes of the public consultation meetings, synthesis of recommendations); decisions approved; annual report of public authorities on transparency in the decision making process.

Law No. 235 stipulates that regulations shall be recorded in the State Registry of Legal Acts following their publication in the Official Gazette of the Republic of Moldova, in compliance

with the legislation. The Registry is kept by the Ministry of Justice. The access to the Registry through internet is free of charge and it can be accessed at <http://lex.justice.md>

Principle of regulatory impact assessment

Pursuant to Law No. 235, regulatory impact assessment represents an argumentation based on the cost/benefit analysis of the need for adopting a regulation and analysis of its impact on entrepreneurial activity, including of the observance of rights and interests of entrepreneurs and the state, as well as of the compliance of the regulations with the regulatory policy goals and principles of this law. The regulatory impact assessment document is an integral part of the information note to the draft regulation.

Proceeding from the above, when a draft regulation on entrepreneurial activity is planned for initiation, it is mandatory to develop a RIA in order to provide arguments for development and approval of such draft regulation. More details about RIA are presented in the other sections of this manual.

Principle of fairness (proportionality)

This principle signifies the following key aspects in regulating entrepreneurial activity:

- a balance and proportionality for insuring the interests of the society and protecting the entrepreneurs' rights;
- restrictions in business registration, operation, and liquidation, free competition, trade and investments are justified by protection of public interest;
- control over the entrepreneurial activity within the limits of and according to the competencies set forth by law;
- suspension of the entrepreneurial activity through court decision, approved under the law.

The RIA on a draft regulation must provide the necessary arguments that would prove the observance of fairness principle in the regulation and/or justify the protection of public interest in some cases. The provisions stipulating that the limits and competencies for controlling the entrepreneurial activity shall be established only through law and the conditions for suspending entrepreneurial activity that would be provided for only in the law should be also taken into account. According to the general rule, entrepreneurial activity is suspended through court decision, and only in cases expressly stipulated by law can an entrepreneurial activity be suspended upon subsequent request to court by the authority that ordered the suspension, under conditions of Law No. 235.

Principles of entrepreneurial activity authorization

Law No. 235 stipulates that a business shall be initiated and/or operated on basis of an authorization, if the law provides for such thing. The law stipulates that the authorization is an action through which the public administration authority or institution empowered through law with regulation and control functions allows the applicant to initiate and/or operate a business, issuing to the latter an act of permissive character, in form of a license – for the types of activity provided for in the Law on Regulation through Licensing of Entrepreneurial Activity No. 451 of

30.07.2001 and/or in form of a permit – for confirming certain technical requirements, separate norms under a certain aspect established by law. The term authorization includes: authorizations, permits, certificates, reviews, approvals, coordination acts, patents, qualification certificates issued by public administration authorities or institutions empowered through law with regulatory and control functions.

Law No. 160 establishes the List of permits – official list of permits where the validity term, fee to be collected, and issuing authorities empowered with the right to issue such permits are specified. It is important to remember that, pursuant to Law No. 160, issuing authorities have the right to request/issue and invoke to persons carrying out entrepreneurial activity or employees of the latter only permits set forth in the List of permits. In case of an intention to establish a new permit, the List shall be completed, by establishing through law the conditions and procedures for issuing respective document.

The key principles of regulation through authorization of the entrepreneurial activity are:

- a) equality of rights and legitimate interests of all the physical and legal entities carrying out entrepreneurial activity or another type of activity provided for by law, which conditions the initiation and/or operation of entrepreneurial activity in a certain area;
- b) transparency and predictability of permits documents required for the initiation, operation and/or discontinuation of entrepreneurial activity;
- c) transparency in decision making on authorization of entrepreneurial activity;
- d) material and procedural regulation through legislative acts of the conditions and procedures for regulation through authorization of entrepreneurial activity;
- e) charging of fees for the issuance of permits only in cases when the amount of such fee is expressly provided for by law or can be established/calculated on basis of the provisions of a legislative act. In all other cases the permits are issued for free;
- f) declaration by the applicant requesting a permit upon own responsibility for the observance of conditions provided for by law and by the regulatory framework on one-stop shops;
- g) tacit approval in case when the issuing authority exceeds the deadline established by law for the issuance, extension, and repeated issuance of permits in the absence of a written statement on its rejection, with the exceptions provided for by the current law and other laws expressly regulating the authorized activities;
- h) fairness (proportionality) between the interests of the society and the rights of applicants upon carrying out control over the observance of authorization conditions, as well as upon suspension/withdrawal of permits;
- i) use of one-stop shop – issuing authorities, in cooperation with other authorities with public functions are obligated to institute and maintain the functionality of one-stop shops required for issuing permits, in compliance with the regulatory framework on one-stop shops.

Quality standards according to RIA Methodology

Finally, we will mention the provisions of RIA Methodology, according to which all the regulations should meet the following quality standards:

- **stability** – regulations are based on market requirements and are subject to principles of predictability, transparency in decision making and regulatory transparency. Regulations that

establish restrictions in registration, operation, and liquidation of a business, free competition, trade and investments are justified through protection of public interest;

- ***cost effectiveness*** – regulations must opt for the lowest cost solution of a clearly defined problem;
- ***flexibility and performance orientation*** – regulations establish the performances that should be achieved by those affected and cannot be justified through implementation of techniques and methods required for achieving such performances;
- ***proportionality*** – regulations should be proportional to insuring the interests of the society and protecting the rights of entrepreneurs.

3 RIA PROCESS

RIA process represents specific actions of certain institutions, regulated and institutionalized mainly for the purpose of drafting and finalizing the RIA and draft regulation, which require covering some stages of this process. In some cases, the stages of RIA process are determined by specific timeframes, while in other cases the stages are carried out depending on the complexity of tasks and goals. On the one hand, the RIA process establishes specific timeframes for the examination and review of RIA and draft regulation by some authorities and entities in order to not delay the decision making. On the other hand, RIA process should provide possibilities for the subjects to contribute to improving the examined documents.

Subjects of RIA process

The RIA process involves a broad range of persons and entities. The most numerous participants are those involved in consultations, and can vary from case to case, depending on the complexity and importance of the area subject to consideration.

First of all, the key RIA process participants are the authors of RIA and of the draft regulation. The authors are usually persons or departments within public authorities who intend to explore the possibility to initiate a state action in solving certain public problems. The authors can constitute a working group for developing the RIA and draft regulation that can include persons both from within the public authorities, and from outside the latter.

Another participant of RIA process is the representative of the public authority responsible for RIA. GR No. 1230 on Approving RIA Methodology establishes that central and local public administration authorities shall assign persons responsible for RIA implementation. That person shall coordinate the implementation of RIA within the authority and provide methodological support to the authors.

A key participant in the RIA process is the Working Group for Regulating Entrepreneurial Activity, constituted on parity principle from representatives of public and private sectors. The term of a WG member mandate is not limited in time. GR No. 1429 stipulates a number of duties for the WG and rights for its members in examination of various problems related to regulation of entrepreneurial activity. The WG convenes in ordinary meetings at least once a week. WG meetings are open to the public.

The Regulatory Impact Assessment (RIA) Secretariat is an important participant in the RIA process. RIA Secretariat includes consultants (experts) from public or private sector and civil servants from the Ministry of Economy. The consultants (experts) assist the WG based on the principles of independence and impartiality. The opinions of consultants (experts) bear a consultative character and are prepared on basis of principles for regulating entrepreneurial activity.

The private sector can intervene at any stage of the RIA process by organizing round table discussions, expressing objections and recommendations on drafted and approved documents. Entrepreneurs may participate in the process individually or through their representatives, including through their associations. RIA and draft regulation authors must identify and collaborate with a broader range of representatives from the private sector.

Participants in the RIA process also include central and local administrative authorities. The latter can intervene at different stages of the process by participating in consultations through various methods, including examination of documents and drafting reviews on the latter.

Initiation of RIA development process

RIA development process can be initiated for different reasons. One of these is identification of a situation, state of things that cannot be tolerated and requires examination and intervention. In such case, the hierarchically superior person is informed about the identification of such situation. Also, each authority is responsible for carrying out a plan for drafting regulations, including for the harmonization of legislation. Another reason for initiating the process, in line with the law, is the decision or indication of officials for developing a draft regulation. Regardless of the reason, prior to drafting such regulations it is necessary to initiate a RIA development process, justifying through it the need for drafting such regulations.

At this stage, the decision is coordinated with the person responsible for the RIA from within the public authority, and then a working group is established for drafting the RIA. The working group is made up of specialists from the regulated sector, economists, lawyers, and other persons, if needed. A small permanent working group can be created that will be provided ad-hoc assistance by specialists in different areas. It is necessary to identify the coordinator of the working group.

RIA drafting activities are usually planned at this stage. The plan must be as detailed as possible, and cover all the stages and activities for each stage, and coordinated with the person responsible for RIA.

This stage of the process involves consultations and communication with various persons inside and outside the institution.

RIA planning

RIA planning is important for several reasons. Firstly, it creates a unique perception of the time limit available for settling the problem. Thus, the goal and ways of achieving it are outlined in time. Secondly, RIA planning imposes a higher degree of responsibility on behalf of all the stakeholders involved. We can also state that RIA planning constitutes a management and monitoring element which allows tracking in time the progress achieved in RIA planning. RIA plan is developed by the RIA working group.

Consultations and communication are especially important in the planning process, as they allow identifying everything that is required to accomplish the set forth goals. First, in-house

consultations should take place, insuring a continuous information flow between the team members and the decision makers. It is important for the information to be specific and up-to-date. External consultations should first be held with the target group, beneficiary of the regulation, final beneficiaries, and civil society in general. RIA is an interactive process. The key allies in the RIA process are: the economists and lawyers from within your unit, institution; the person responsible for RIA within your institution; the legal directorate of your institution; key information suppliers from private sector, civil society and academic sector; central and local public authorities; and the RIA Secretariat.

At the beginning of the RIA process discuss the information you already know and test your assumptions with colleagues. Also identify information gaps – additional information that you still need. Get involved in informal consultation with stakeholders from within your institution and from outside.

After preliminary planning, agree upon an Action Plan for RIA. For this, identify the information sources, consider what support you will need, and identify the key stakeholders – make an analysis of stakeholder, plan for a consultation approach – use different consultation methods.

Preparation of preliminary RIA

Before starting to prepare the preliminary RIA it is necessary to carry out consultations with different persons. It is also necessary to collect information from various sources – manuals, monographs, scientific articles, reports, statistic data, etc. RIA preparation will start with the drafting and coordination of RIA structure with the team, and, if needed, with the person responsible for RIA within the public institution. RIA structure is important in order to have a complete vision on RIA document; it facilitates the process of drafting its contents. At this stage, through key activities relate to the drafting of RIA content. RIA content must comply with the requirements on each RIA component, which will be described in the next chapters of the manual. It is important to remind here about the need for taking into consideration the principles of good regulation, related in the previous chapter. Upon completion of the preliminary RIA, the latter is posted on the website of the authority for information and comments.

Preliminary RIA review by the Working Group (WG)

Preliminary RIAs are mandatorily submitted for examination and review to the WG. This is an important stage of RIA process, as the WG decisions bear official character. Despite the fact that the WG decision is a consultative one for decision makers, it is not neglected.

The review process within the WG is regulated in brief through government resolution. The WG is obligated to consider the materials officially sent to it within 10 days. This time is necessary for each WG member, as well as for other interested persons, to have the possibility to consider and analyze the materials constituting a subject matter of the agenda. At the same time, this deadline does not allow delaying the examination of documents and approval of a decision. The WG members are notified about the meeting agenda at least one week prior to the date of the meeting, via e-mail, at the address provided by each member. While exercising their duties, the WG members have the right to request information required for carrying out their activity from

public administration authorities; to invite specialists to provide consultations on subjects included in the agenda; to request putting the forwarded proposals to vote. Depending on the issues included in the agenda, representatives of other organizations/departments can be involved in the WG activity. WG decisions are approved through a majority of votes of the members attending the meeting. In case of a tie vote, the document is considered as negatively reviewed. Separate opinions of members and experts are attached to the minutes.

The WG decision can be stated in one of the following versions:

- a) rejecting the development of draft regulation without carrying out an additional analysis;
- b) accepting the development of draft regulation without carrying out an additional analysis;
- c) studying in details the opportunity of the draft regulation according to the final regulatory impact analysis (assessment).

In case of the decision stated under item a), RIA is rejected, and, therefore, no regulation can be drafted. Efforts are required from the authors to improve the RIA content, providing arguments in favor of the need for drafting such a regulation. The improved RIA is submitted in the general manner to the WG for review. Another option can be for the authors to decline to carry out additional analysis and, respectively, to decline the drafting of regulation.

In case of the decision stated under item b), the authors can draft the regulation, the need for which has been justified in the RIA. The preliminary RIA will be sufficient for supporting the draft regulation in continuation. In some cases, the WG can request that the preliminary RIA be improved and submitted concurrently with the already drafted regulation for review.

In case of the decision stated under letter c), the authors must develop the draft regulation together with the final RIA. Final RIA will respond to some additional questions, which will allow adopting the decision regarding the opportunity of respective draft regulation.

Drafting of the regulation and final RIA

A draft regulation is developed if the WG approves a decision on drafting such regulation. When developing the draft regulation, likewise in the stage of RIA drafting, it is necessary to take into account the principles of good regulation. In addition, the draft regulation should be developed by taking into consideration the provisions set forth in Law No. 780 and Law No. 317.

The final RIA will be developed concurrently with the draft regulation based on the WG decision. Consultations, including obtaining the necessary information, are required in the process of drafting the regulation and preparing the final RIA.

Legal review and public consultations

Upon completion, the draft regulation and RIA must be posted on the website of respective authority. Thus, each stakeholder will have the possibility to become familiar with respective documents and express their comments and recommendations in different forms. The draft regulation and RIA are officially sent to interested public authorities for review. In particular, it is necessary to identify and inform about the existence of respective documents the target groups

on which, in the authors' opinion, the draft regulation will have a considerable impact. In this context, it is advisable to get a review on these documents from relevant business associations, as well as from other interested persons. At this stage, consultations with public authorities, RIA Secretariat, and other interested persons can contribute to the improvement of the regulation and of other documents. Following the review of the regulation and RIA by private sector and public authorities, except for the Ministry of Justice, the documents shall be examined by the WG. The procedure and conditions for examining documents within the WG meetings is similar with those applying to preliminary RIA, which justifies the development of such draft regulation. The WG decision can be positive or negative. If the WG provides a negative review, the authors can make amendments to the draft and request for a new examination in one of the WG meetings.

Following the review of the draft regulation by the WG, the document must be submitted to the Ministry of Justice for review. The legal review of documents by the Ministry of Justice, including verification of the requirements for complying with the European legislation finalizes the review process.

Completion of the draft regulation and RIA

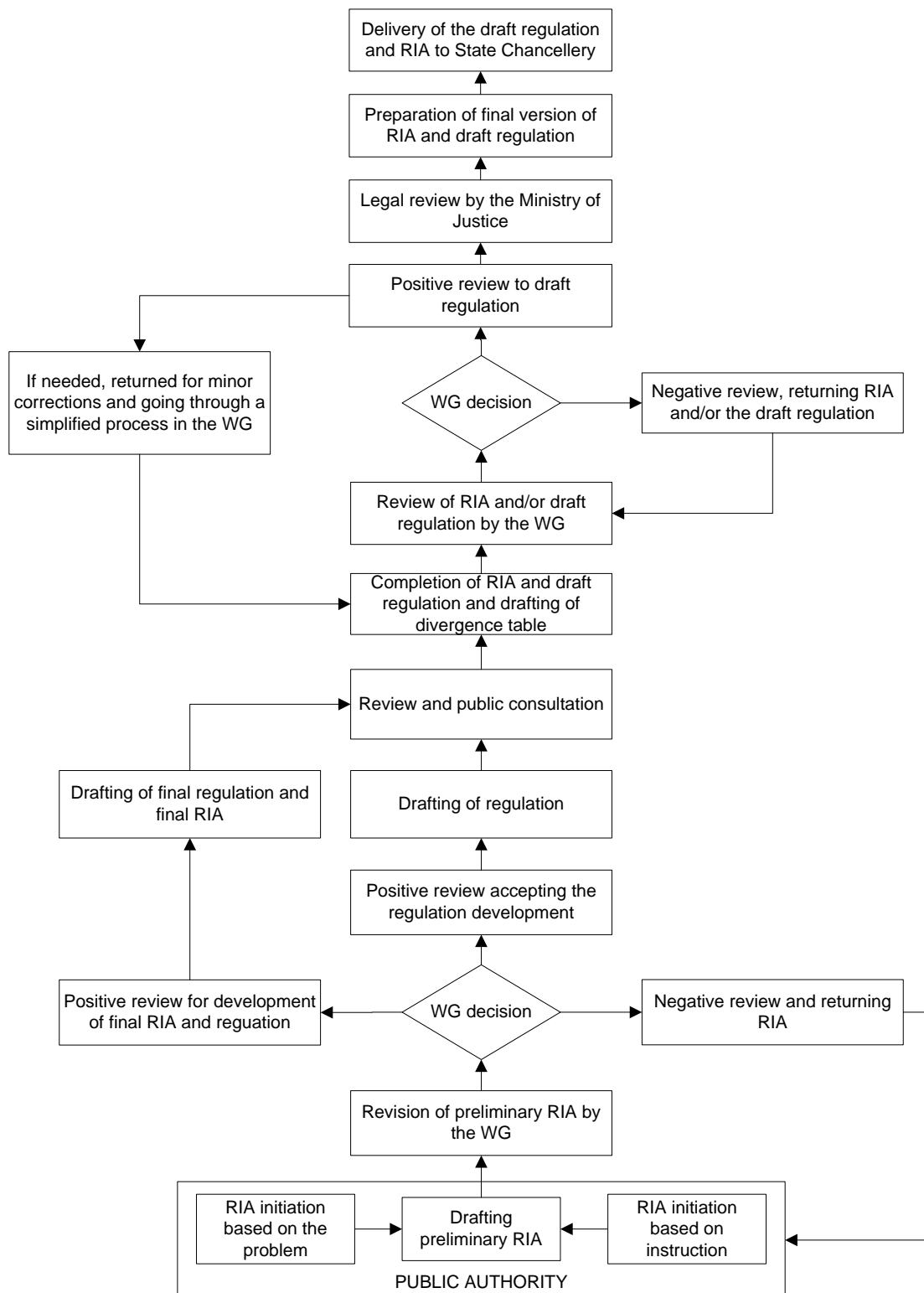
At the stage of review and public consultations, before examination by the WG, the draft regulation can be amended according to recommendations. The reviews by public authorities, business associations, and other interested persons are examined by the authors, followed by drafting a divergence table, in which the authors state their agreement or disagreement with the reviews and recommendations received. In case of disagreement, the authors should provide explanations and arguments. Following the examination of reviews, preparation of the divergence table, amendment of the draft regulation, and, as the case may be, of the RIA, all these documents are submitted to the WG. In some cases, during the WG meeting, the authors state that they would take into consideration the recommendations expressed and make necessary amendments to the draft regulation. In such situations, a decision can be approved for providing a positive review on the given draft regulation, under the condition that the authors will make respective amendments and submit the finalized draft regulation and RIA to RIA Secretariat, which will verify and send them to the WG members for information.

Preparation of the final draft regulations and RIA

Following the stage of legal review, examination and finalization of the draft regulation, including by the Ministry of Justice, the final version is prepared. At this stage, consultations with the RIA Secretariat are required, and, as the case may be, the final documents are submitted to the RIA Secretariat for information. The final documents are submitted to the State Chancellery or to the responsible unit within the local public authority that examines and promotes the documents in compliance with the legislation.

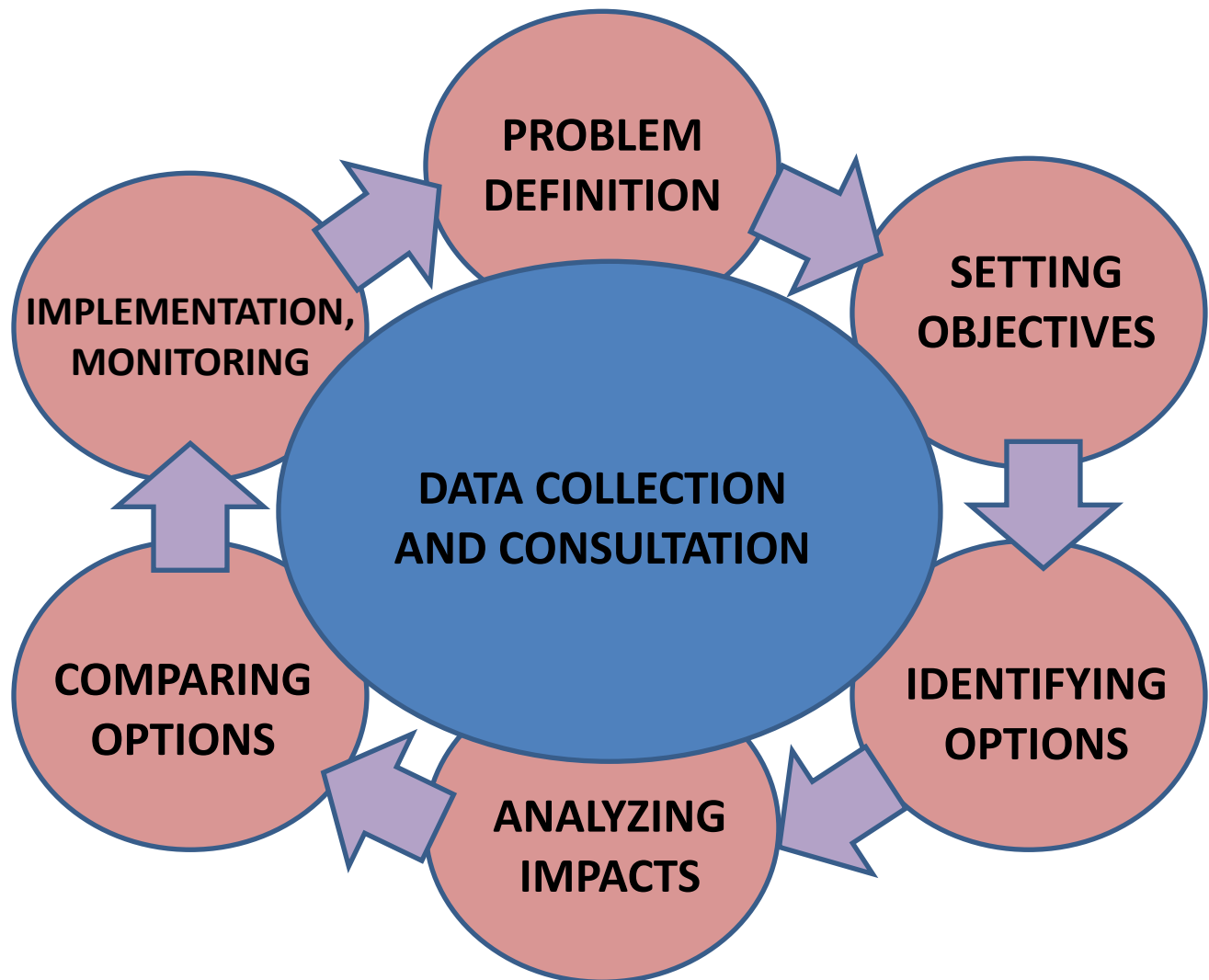
RIA process chart

RIA process chart is presented bellow, including all the steps described above.



4 RIA STAGES AND ELEMENTS

According to the best international practices, RIA includes several distinctive key components that contribute to the purpose of this process, i.e. development of quality policies/regulations. These elements can be graphically presented as follows:



The key elements of RIA process are:

- data collection and consultation, represented in the center of the chart above, takes place during the process practically for each RIA element;
- problem definition is the first RIA step, and therefore, the key element on which the quality of exploring the other elements depends;
- setting of objectives establishes the degree of ambition for settling the problem and helps both in identifying the options, as well as in assessing the effectiveness of options during the implementation stage, which depends on the degree to which objectives are accomplished;

- identification of options, which are designed to achieve the objectives, and resolve the problem;
- analysis of the impacts of options, both their costs and benefits, in order to be able to select the most favorable option;
- comparison of options based on their impacts, by applying certain decision making criteria, and, as a result – recommendation of the most favorable option;
- description of how the implementation and monitoring process will be organized for the recommended option, which will demonstrate that the proposed option is realistic, and its effects can be evaluated in the implementation process.

It is important to mention that covering the RIA stages and developing its elements constitute a live and iterative process, which means that at each stage, you can get back to the previous stages and review/improve them, if you consider it necessary. For example, as a result of the impact analysis, you could find out that you did not fix the objectives realistically, and should revise them.

The manual contains separate chapter for these elements, which are described in more detail, and explained through specific examples.

In principle, both RIA Methodology and Ex-ante Guideline² in Moldova contain these components, with some specific characteristics. The chapter on proportionality of analysis indicates the way in which RIA elements are reflected in the Moldovan RIA Methodology, depending on the type of RIA, i.e. preliminary RIA and final RIA.

4.1 DATA COLLECTION AND CONSULTATION

The key quality criteria for data collection and consultation are:

- RIA shall be based on evidence.
- All relevant ministries, agencies, and institutions shall be consulted adequately.
- External stakeholders, such as citizens, civil society, and businesses shall be consulted at required RIA stages and provided sufficient time to respond.
- RIA shall register the responses from consultations and explain if the consultation results have been used.
- RIA shall be published for consultations.

Data collection

Data needs should be identified at an incipient stage of the RIA process. In some cases, part of the data can be available in the institution initiating the RIA development. For example, in the monitoring and evaluation reports on similar activities and areas, in the previously developed RIAs, studies and researches, statistical data, information collected from stakeholders (round table discussions, conferences, etc.) and others. In other cases, it is good to consult other public

² State Chancellery is piloting a draft Methodological Guideline for Ex-ante Assessment of the Impact of Public Policies, which is described in the introductory part.

institutions and stakeholders from the private sector in order to collect data. It is recommended to contact and establish cooperation with respective stakeholders in advance. In addition, it might be advisable to involve independent experts to carry out some data collection and analysis work. It is also important to use the official data available within the state bodies, including those provided by the National Statistics Bureau.

It is also beneficial to search for examples of good practice from other countries and recommendations of international organizations (especially those from the World Bank, and OECD). RIAs from other countries and those developed by the European Commission could also be good sources. These can be found on the web pages indicated in the chapter on support for RIA development.

Proceeding from the resource, data, and time limit, you can apply the principle of proportionality in data collection, which means that in some situations, assumptions can be made on the basis of expert opinions; examples from other countries and other areas in order to supplement the lack of data. If such assumptions have been made, these should be clearly explained in the RIA document.

In the process of data collection, it is important to take into account the planning made in the beginning of the analysis process in order to be able to focus the efforts on data that is relevant for the analysis and narrow the searches. At the same time, it should be kept in mind that data collection is an on-going process lasting throughout the entire RIA process, including during the stage of monitoring the performance of the regulation.

To insure credibility of the analysis, the RIA document must provide data sources on the basis of which the analysis has been carried out.

The RIA Guidelines of the European Commission and Great Britain provide link to guidelines specialized in data gathering and consultation which provide more details on techniques and methods on this subject.

Consultation

Consultation on RIA is mandatory, and it is designed to insure the development of a better quality RIA, and, eventually, of a better quality regulation. While carrying out consultations, the RIA process, described in a separate chapter above, should be taken into account.

It is important to consult with the relevant ministries and agencies that can provide data or influence the analyzed area and options. The ministries could help conduct a better quality analysis of the fiscal, social, economic, and environmental impacts. Moreover, some implementing institutions could provide important data about the compliance level and implementation/enforcement capacities for different options.

External stakeholders (citizens, civil society, and business environment) should be consulted as well. Following the identification of key stakeholders, it is important to apply a consultation strategy, because it might be necessary to involve the stakeholders at different RIA stages, including in problem definition, elaboration of options and impact assessment. Moreover,

different stakeholders require different consultation methods and different timeframes for providing feedback.

As a result of consultations, RIA should record the stakeholders' responses and explain if the consultation results have been used within the chapter reserved specially for this (according to the RIA Methodology). This will improve the quality of RIA document and will provide a higher credibility, respecting the requirements set in the Methodology with regard to consultation strategy and process.

Finally, the RIA should be published for feedback. The document should be posted on the official webpage of the author public authority, by providing sufficient time for feedback. The recommended timeframe for public consultations is at least 30 days. At the same time, for a higher efficiency, the authors should not base mainly on this type of passive consultation, but rather focus on active consultation with the affected and interested parties through meetings and direct communication.

4.2 PROBLEM DEFINITION

Problem definition is the first RIA element. It is crucial to define the problem correctly because no analysis can compensate for a poor problem definition. The analysis in such case could evolve in a wrong direction, and the government intervention could finally turn into a failure. In the best case, the failure of the intervention could show through the fact that the regulation fails to have the desired effect. In the worst case, an intervention based on a wrong problem definition could worsen the problem and/or create other problems.

The key quality criteria in problem definition are:

- RIA shall include a clear description of the problem that is based on evidence and justifies the intervention.
- RIA shall describe the current policies/regulations affecting the problem.
- The magnitude of the problem shall be quantified to the extent possible. If not quantified, the reason shall be explained. It is necessary to apply the principle of proportionality, which means that the preliminary RIA requires less quantification than the final RIA or that less important problems required less quantification.
- Problem causes shall be clearly identified.
- The problem shall not be defined as the lack of an action or the lack of a regulation.

4.2.1 Problem analysis process

Problem nature

Problem analysis should start from understanding the problem and clearly delimiting it based on some evidence/data. It is important to start from an unwanted public situation that the public authority could intervene in order to correct it, or from a public situation that the public authority would like to maintain. Usually, an unwanted situation implies a market or a regulatory failure

that is taking place, which is indicated by the stakeholders or found out as a result of analyzing the situation in dynamics or in comparison with other countries. More details about the market and regulatory failures are presented in a separate chapter below.

Magnitude of the problem

Further on, it is useful to estimate the problem magnitude in some quantitative or value units. This allows us to understand the proportion of the problem for applying the principle of proportionality in approving the decision on government intervention. Moreover, the quantitative estimation allows us to set clear objectives we want to achieve and, subsequently, to monitor and evaluate if we have achieved the objectives and settled the problem.

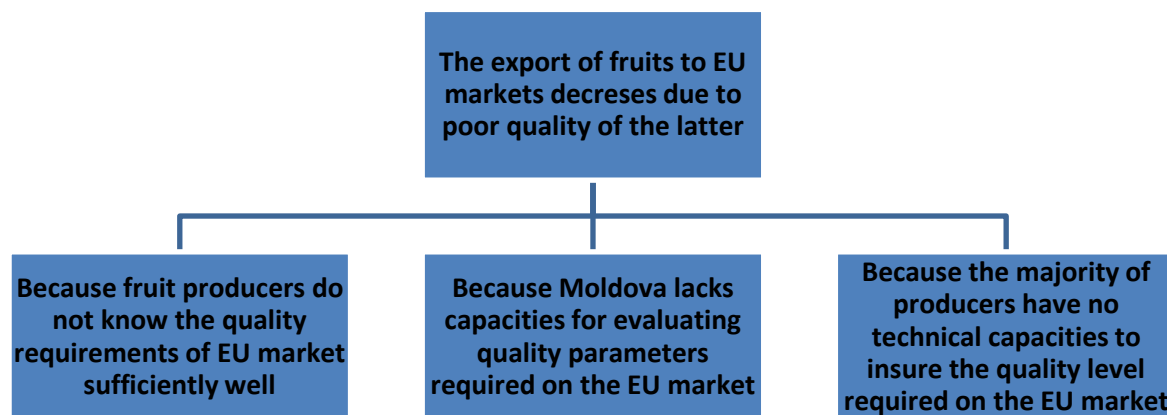
Example of quantified problem: It has been scientifically demonstrated that a concentration higher than 300 mg/kg of lead in the soil constitutes a high risk of environment pollution and affecting the population's health. This concentration was exceeded by over 30% on the analyzed land lots.

Problem effects and causes

The unwanted situation presented above also generates unwanted effects. The effects caused by the problem indicate the potential of existing benefits in case of settling the problem. But the causes of the problem constitute the most important thing to be identified in this chapter. In fact, the actions designed to resolve the problem are directed towards the causes, which, if eliminated, would lead to problem settlement. If the causes are not identified, the proposed actions directed towards the problem could have the character of some symptomatic actions which will not resolve the causes, and the problem could shortly reappear, or even worse, the problem could aggravate significantly, which occurrence would be called regulatory failure.

In order to demonstrate more clearly the regulatory failure in case of a faulty problem definition, we will use the “problem tree” method. For example, agricultural producers grow fruits that to a large extent do not comply with the quality requirements on the EU markets. For these reasons, after several attempts to import quality products from Moldova, the importers from EU countries started giving up such attempts. If the problem is not analyzed sufficiently and the main causes leading to these effects (symptoms) are not identified, the government could react symptomatically. A symptomatic solution might be imposing the observance of some quality parameters through a regulation. However, if the cause of this problem resides in the fact that the majority of the producers have no technical capacities for insuring the quality level required by the EU market, such regulation could lead to the bankruptcy of many producers. Moreover, symptomatic solutions of such type could have some undesirable social effects, causing increases in price and reducing the offer of fruits on the local market, which would affect in particular the disfavored segments of the society.

The tree of the given problem can be schematically presented as follows:



It would be ideal to try and determine the share of each cause in generating the problem. In this way, the effort for settling the problem would be streamlined towards the major cause, without wasting the resources of government and of the society. If the main cause is the lack of technical capacities, the government should intervene in this sense by facilitating access to financing for purchasing the necessary equipment and technology, providing exemption from taxes and fees, etc. In this way, the main cause would be eliminated, which would have a symptomatic effect reflected through growth of fruit exports, and therefore, the main problem settled.

It is important to mention here that defining the problem and its causes should avoid the assumption of an intervention. These should not be defined as “lack of an action” or “the need for undertaking a certain action”, because it would incline the analysis towards only one option, which may not be a reasonable option or the most cost-efficient solution. We should also avoid the stipulation that the lack of a regulation is a problem, because the regulation is only one of the possible (alternative) options for settling a problem.

Policies and the existing normative framework, and how these affect the problem (legal component)

It is important to separately analyze the current legal and strategic framework related to the stated problem. This starts with analyzing the actions taken by the government in the past for settling respective problem or similar problems. In this way, we will avoid eventual overlapping of actions for solving the problem. Moreover, we will determine the effectiveness and efficiency level of previous measures, which would allow developing less costly and more effective actions in the future. Thus, it is important to find out all the normative and legislative acts regulating the analyzed area (subject) and analyze the latter in order to determine drawbacks in the current regulation.

In addition, it is important to analyze within the strategic framework and Moldova’s commitment before foreign partners, in order to know how this problem could evolve in the future. Some actions could have already been proposed in some action plans or harmonization plans, being considered as a component part of the reference scenario described below. However, even if some actions are provided in some plans or current regulations, it doesn’t mean that the latter are exempt from an analysis of effects on the identified problem. RIA Methodology does not make

exceptions in such cases. Moreover, RIA can provide evidence and justifications for amending some regulations through which such action plans or approximation plans were established.

Estimating the reference scenario or how the problem could evolve in the future if no additional actions are taken

After the problem has been clearly identified, including its causes, it is important to assess its evolution in time, i.e. what will happen if no additional intervention is made for settling it. Such evolution is also called base scenario or reference scenario or “status quo” / „do nothing” option. The assessment of this scenario allows us to understand if the problem persists in time, as it could happen that the problematic situation is temporary and will disappear by itself in a reasonable time. In such cases, the conclusion could be for the government to not intervene. However, if the problem persists or even intensifies, the base scenario will allow us to assess the impacts of options proposed for settling the problem, because they are aimed at changing the situation in the base scenario.

More details about impact assessment, having the base scenario as a reference, are provided in the chapter on impact assessment.

Justifying the government intervention

By government intervention we mean one or several actions that the government takes with the aim for settling one or several problems for the society. The intervention may be of regulatory character, through which certain rules might be imposed with the aim for changing the behavior of citizens and businesses, which would lead to settling some public problems. On the other extreme are the interventions of voluntary character, through which the government is trying to get a voluntary agreement with the stakeholders, so that the identified problem be settled. More details about the types of government interventions are described in the chapter on options.

Both theory and experience of other countries suggest that the government intervention through regulation should be avoided to the extent possible, because this involves costs and can distort the functioning of market economy, generating undesired effects or even failing. Thus, the government intervention in a market economy could be justified by the need for eliminating a market or regulatory failure that impedes the efficient functioning of economy or by the need for insuring fair access to resources/welfare for certain categories of the population or businesses. More details in this sense are presented in the chapter on reasons for government interventions. In addition to identification of the current undesirable situation, it is necessary to demonstrate that the situation won't improve much in the future, i.e. the problem won't disappear by itself, and that the problem causes are well-known, so that the developed actions will be well-targeted and not symptomatic, being able to bring the expected effect.

4.2.2 Problem definition when the intervention is prescribed, including in the case of harmonization with the EU legislation

In addition to reasons of the above stated intervention, there are a number of situations when the intervention is prescribed by a current regulation or a public policy document, such as strategy, program, and plan for drafting regulations or commitment assumed in relations with the international organizations. This category of situations includes the process of legislation harmonization with the EU legislation. However, it is important to mention that, although the intervention is prescribed, the process does not spare the authors of the intervention from drafting a RIA through which to analyze the addressed problem. If the prescription comes from a regulation, it doesn't mean that the given regulation cannot be reviewed as a result of an additional corresponding analysis. It might happen that the act prescribing the intervention has lost its relevance or creates more problems than those undertaken to be resolved, without basing on an analysis at the moment of its development. Thus, RIA could conclude that the prescribed intervention is no longer required, therefore the review of the act prescribing it could be recommended. The situation might be similar in the case of some policy documents prescribing interventions. As regards the commitment in relations with international organizations, the latter should be preceded by a proper analysis. However, even if these cannot be avoided, including in the situation of legislation harmonization, RIA cannot lose its importance; moreover, it should respond to questions, such as the following: What is the most optimal way to implement the given legislation? What would be the implementation timeframe? What are the proper instruments for the implementation and accomplishment of the goal stated in the commitment? More details on this subject are presented in the chapter on options.

Even in the case of harmonization with the EU legislation it is important to clearly define the situation that the government undertakes to improve through implementing the provisions of EU legislation. In such cases it is recommended to start by describing the problem at the basis of European legislation. RIAs developed by the European Commission for the EU legislation could be of help here. References to the webpage containing RIAs developed by the Commission are provided in the chapter on support for RIA development. Then, the Moldovan situation in this regard and the current national legislation should be studied in order to identify the changes required for harmonization and to go through the steps for problem analysis, described above.

4.2.3 Reasons for government intervention

4.2.3.1 Market failures

In an authentic market economy, the benefits of the society are maximized, because the market creates the offer of goods and services requested by the population and the information about existing products and services is transparent so that the consumers can make optimal decisions, which, in their turn, ensures a fair competition and put pressure on companies to improve the offer. As a result, businesses are motivated to constantly improve the quality of products/services, at the same time improving the production/delivery processes and thus reducing the price of products/services. However, due to some unfavorable circumstances, the market can fail in offering quality products/services, as a consequence generating some problems for the society. In such cases, the government intervention could be justified, but the latter should be well thought out and efficient in resolving the problem, because the government may also fail

in the attempt to settle some problem. The key market failures that could justify the government intervention are presented below:

1. Insufficient supply of public goods

The market might have problems in delivering some types of goods and services, which are called public goods. The key characteristics of public goods are:

- the consumption of a public good by a person does not reduce the quantity available for the consumption of other persons, and
- the public good once offered, is available for consumption by the entire society.

It is difficult and/or undesirable from the point of view of the society to be charged payment directly for the consumption of the given good, as the non-regulated markets will offer small quantities of the collective good, if at all. Examples of collective goods are: clean air, public roads, and national defense. In agriculture we could mention anti-hail land protection as a public good, provided by the Special Service for Active Influences on Hydrometeorology Processes, which is funded from the state budget.

2. Market prices do not reflect the real costs to society (externalities)

Private activity could have certain effects, called externalities. Externalities generate costs and benefits that are not reflected in the market price of the private activity products. In case of externalities in form of costs, such as pollution, it means that we tend to produce and consume too many goods and services that generate externalities, because these goods/services do not include the pollution costs, and, respectively, are cheaper than they should be. An example in this sense could be the wastes generated by agricultural producers that are stored in unauthorized public places, without incurring any costs. Thus, the costs associated with the collection and processing of respective wastes are externalities incurred by the society and are not reflected in the price of final products, the consumption of respective products being much higher than in the case when the pollution costs would be included in their price. Another example would be when a company would maintain the costs at a low level, without investing in water pollution control systems, at the same time transferring these costs to companies and persons using the polluted water. As a result, the polluter imposes external costs on other water users.

3. Information asymmetry

Information is necessary for the efficient functioning of the market. The customers need to know the quality of the good or services in order to judge the benefits that the latter can offer them. In their turn, vendors, creditors, and investors need to know the credibility level of customers, debtors or entrepreneurs to estimate their need for confidence.

The information should be sufficiently available for both buyers and sellers. If information is unavailable, the market could fail. This situation is known as „information asymmetry” and can take place in situations when, for example, the vendors have the information about some aspects of the product that the customer doesn’t know. The asymmetric possession of information can lead to problems of “adverse selection” type, which are characterized by encouragement of lower

quality goods and services and withdrawal from the market of quality goods and services due to the lack of information on behalf of the customer, the latter making a poor informed and inefficient choice, which is implicitly an insurmountable barrier to the development of effective competition. An example would be if the customer did not know about energy efficiency of the refrigeration equipment, and tended to buy what is cheaper in price, but which turned out more costly in operation over a medium term.

4. Lack or insufficiency of competition

In a sound competitive market economy, the economic resources are allocated efficiently. If the companies are not faced with competition or if the competition is weak, then the companies tend to take advantage of this situation, while the quantity and quality of offered products could deviate from an efficient level.

The high costs of entering into a business, which can be imposed by the companies already existing in the market could limit the number of companies operating in this area and could finally lead to market failure. Examples of this kind could be when the companies invest in any additional capacities available on the market or involve in competition restriction practices by establishing low prices, even below the product cost in order to get rid of the competition and to subsequently raise the prices at a desirable level when they remain as the ones dominating on the market.

5. Missing or incomplete markets

In some cases, the market cannot put goods and services at the disposal of the society, even if these are necessary. Other goods and services could be delivered under restrictive conditions. For example, small enterprises and individual entrepreneurs could face difficulties in obtaining bank loans in case when the banks require considerable loan coverage with collateral.

4.2.3.2 Regulatory failure

Government actions can also lead to undesirable results for the society. These are called regulatory failures. In fact, keeping in mind that the areas and relations in the society are to the biggest extent regulated, the majority of problems emerge as a result of already existing regulations. Moreover, for Moldova, as an open economy, it is important to work on reducing to the maximum extent feasible the costs to the economy generated by regulations, and insuring a favorable environment for the development of competitive businesses and attracting investments. This is also important in the context of the process of harmonizing the national legislation with the European Union legislation, which currently constitutes a big part of the effort for drafting Moldovan regulations. You can find presented below the most important regulatory failures.

1. Inadequate definition of property rights

A well-functioning of the market economy depends on the existence of some clearly defined and acknowledges property rights. Thus, you won't be willing to purchase a real estate good if the

person from who you are purchasing it would have the right to take it back without being penalized or sanctioned correspondingly for this act.

2. Poor or unclear definition of the problem and objectives

The poor and unclear definition of the problem and objectives of government intervention can lead to selection of a wrong solution. A wrong solution, in the best case, would mean an intervention that does not bring the desired effect, like a regulation remaining only on paper or having effect on other situations rather than on the desired one. In the worst case, a wrong solution could lead to problem worsening and/or could create other problems. For a better understanding of how mistakes can be made while defining the problem and setting the objectives, please see the chapters describing the problem definition and objectives setting stages.

3. Unintended consequences, such as barriers in entering into or expending a business

In their effort to settle the problem, public authorities could cause some undesirable effects for the society. For example, they could create barriers to business initiation in an area, thus protecting the existing companies, even if the new companies could bring in innovations, improve the quality of products and reduce their price. An example of such barrier could be the imposing of some requirements for storage and transportation of certain agricultural products, which would favor the companies holding capacities in this sense, and would limit the competition and reduce the access of the population to cheaper products.

4. “Regulatory capture”

Usually, public authorities do not have sufficient information about the problem they want to settle or about the effects of potential solutions. During the consultation process, some interest groups could influence the decision making process in their favor by supplying the bulk of the information, and manipulating the decision in this way. Hence, we should take into account the fact that some groups in the society, although representing the majority, such as small enterprises, don't have sufficient power to participate effectively in the consultation process, and therefore, public authorities can be “captured” from the information point of view by big companies that have bigger resources and greater possibilities to represent and lobby their interests. As a result, the authorities could approve a regulation favoring only some groups in the society, and disfavoring the other ones.

An example in this sense could be when large agricultural enterprises possessing important agricultural produce storage and transportation capacities would promote the approval of more restrictive conditions in this sense, using various reasons for that, including the risk for consumers, which could be lower than presented by them, and, as a consequence, the government could create even higher costs through limiting the small enterprises, rather than benefits for the consumers.

5. Implementation and enforcement failure

If the actions proposed in regulations were not sufficiently evaluated, these could appear hard to implement and, as a result, the regulation provisions could remain only on paper or generate considerable unexpected costs for the society. These situations would serve as a reason for government intervention to correct the created situation. There are several examples of implementation failures in Moldova, when while rushing to bring the national legislation in line with the EU legislation public authorities practically copy the text of directives without analyzing their impact on and applicability to Moldova's conditions. Thus, the results pursued by these regulations sometimes turn impossible to implement, implementing institutions (inspections and other bodies) continuing to apply the provisions of the previous legislation or allowing discretionary deviations from the new provisions. Although the discretionary behavior is a necessary solution in some cases in order to not lead to liquidation of several enterprises, it has a potential to favor corruption and unfair treatment, thus hindering free competition and causing exaggerated costs for entrepreneurs, and finally, for the society, including limited access to quality products and services and increased prices of the latter.

4.2.3.3 Fairness in access to resources/welfare

In addition to market and regulatory failures, another reason for government intervention can be the insuring of fair access to resources/welfare. An example in this sense can be the Anti-hail Service of Moldova. This Service protects approximately 46% of the agricultural land from hail. Thus, the rest of the agricultural areas are unfairly treated and respective agricultural producers are less competitive. Even though the risk of hail on the areas uncovered by the Anti-hail Service is lower, the risk of losses for the producers is higher compared to the protected areas. Thus, the given situation is distorting the normal market functioning, disfavoring both some regions of the country and some specific producers who become less competitive. As a result, the investments in agricultural production are decreasing in the given regions.

4.3 SETTING OBJECTIVES

After the problem definition, we should set the objectives/goals by which we fix the extent to which we wish to solve the problem. By setting the objectives, RIA authors outline the circumstances and/or situation that they want to reach in the future (desired end state) and not the way by which they want to get there.

The key quality criteria in setting objectives are:

- RIA shall set the key objectives that are linked to the problem and its causes.
- Objectives shall not be set as a need for undertaking an action or a regulation.
- To the extent possible, the objectives shall be measurable and time-bound. The principle of proportionality shall be applied, which means that, the objectives for preliminary RIA can be less measurable and fixed in time as compared to final RIA, or less important issues require less measurable and fixed in time objectives.

The objectives are closely related to the identified problem and causes of the latter, so that the accomplishment of objectives would mean the problem settlement. Setting clear objectives, i.e.

what we want to achieve, would allow us to identify the options for solving the problem. The objectives serve as an important criterion in establishing the intervention effectiveness. Moreover, it is difficult to monitor the intervention implementation without having clearly set objectives.

The objectives should not be set as “a need for taking an action”, as this would incline the analysis only towards one option that might not be a reasonable one or the most cost-efficient (cheap) solution. And neither should the objectives be set as “a need for approving a regulation”, because the regulation is only one of the possible options (alternatives) for settling the problem.

To the extent possible, the objectives should have a value or be measurable and fixed in time, which would allow monitoring the implementation of options and assessing the extent to which respective options produce the desired effects. The principle of proportionality should be also applied, which means that the objectives for preliminary RIA are less measurable and fixed in time as compared to final RIA, or less important issues required less measurable and fixed in time objectives.

Ideally, the objectives are formulated in a SMART manner (Specific, Measurable, Acceptable, Reachable and Time-bound). The chart bellow presents explanations for each of the SMART components:

Specific	• Well defined and clear for anyone possessing basic knowlege in the area, leaving no room for interpretation
Measurable	• Measurable, to be able to determine if it has been achieved or not
Acceptible	• Accepted by the interested parties involved in accomplishing it
Reachable	• Fit into resources, capacities, and time available
Time-bound	• Reasonable time allocated. Allowing to determine if it has been achieved or not

Examples of objectives which are not SMART:

- Increasing the land areas with nitrogen content not exceeding the established level.
- Reducing the intoxication with fruits among children of pre-school age (0-6 years) by the end of 2015.

Examples of objectives that are SMART

- Civil servants employed since 2009 should be trained in regulatory impact assessment by the end of 2010.
- Reducing by 50% the number of food poisoning by tomatoes by 2014.

4.4 IDENTIFYING OPTIONS

Following the problem definition and setting objectives is the stage of identifying options, which are designed to accomplish the objectives and settle the problem.

The key criteria in identifying options are:

- RIA should include the “doing nothing” option /base scenario.
- Identified options shall be clearly linked to the objectives and problem causes.
- RIA shall include the main realistic options, including non-regulatory options, such as information and education, self-regulation, voluntary agreements, etc. If non-regulatory options are not included, the reason for this should be explained.

The approach in solving a problem is as important as the decision to undertake an intervention, because a faulty choice of a solution could lead to a regulatory failure or failure of government intervention. The regulation/legislation³ is not the only solution for settling a problem. Public authorities are traditionally used to settle a problem through regulation, considering other alternatives as very uncertain. However, the experience of other countries demonstrated that the regulations oftentimes created exaggerated and unjustified costs for businesses and society, in general. Moreover, regulatory options do not guarantee changing the situation in the desired manner, some regulations remaining only on paper or compliance with the latter being insured at a very low level. There are different alternatives available as policy options for addressing a public policy problem, which is why hasty conclusions and presumption of intervention type should be avoided.

4.4.1 Stages of identifying options

The following stages are recommended in identifying options:

1. Identify a broad set of credible options related to the objectives and problem causes. If the options are not clearly related to objectives and problem causes, they could move in a wrong direction, and, if implemented, they could be counterproductive or even worsen the undesirable current situation (problem). While identifying options we can use several approaches, including: the experience of other countries in settling similar problems; previous solutions implemented in Moldova in the analyzed area, as well as in other areas; conducting studies and polls to determine possible interventions; consultations with interested/affected parties; involvement of experts specialized in the area under analysis; carrying out pilot exercises to test certain options.
2. Insure that the options, based on preliminary data and knowledge, are able to reach a satisfactory problem settlement and accomplish objectives, otherwise the options are eliminated from the subsequent analysis.

³ In our case, through the term „regulation” we refer to direct prescription of rights and obligations and imposing of a conduct to participants in the deficient social relations analyzed under „problem definition” without pursuing other primary goals than the one that the parties comply with the regulation with regard to the latter (and the sanction that can be applied).

3. Avoid identifying only a “status quo” option, an “extreme” option, and a preferred option. By extreme option we mean an option that is hardly acceptable for several reasons, including budget constraints, capacity constraints, and others. Therefore, only a single option would be acceptable, which might not be the most favorable option in solving the problem. Therefore, only realistic options with a potential for being implemented should be selected from the very start, and only the impact assessment of these will allow selecting the most favorable option.
4. Insure the inclusion of the “do nothing” option, and, if needed, the alternative options to regulation. The “do nothing option” is the base scenario which explains how the current situation will evolve without an additional government intervention. It includes all the interventions already in the process of implementation and those already approved and planned. This option allows us to better understand if the intervention is needed, in case when the situation is evolving unsatisfactorily, and serves as a basis for comparing the alternative options. The alternative options to regulation, such as information and education, self-regulation, and others can reduce the costs and increase the effectiveness of government actions. This is why it is important to take into consideration all the realistic options for settling the problem and accomplishing the objectives.
5. Narrow the number of options based on a general analysis of technical and other constraints. Among constraints can be the already assumed commitments within some international agreements, which do not allow taking some actions, or constraints in terms of budget funds and potentially available institutional capacities. Another type of constraints includes the good regulation principles described in this manual. If the option contradicts one of these principles, it should be eliminated or modified.
6. Clearly explain the reasons for excluding certain options from subsequent analysis. This refers especially to the cases of not including the non-regulatory options.
7. Impact assessment will be carried out for the pre-selected options. The description of impact assessment is presented in a separate chapter.

4.4.2 Types of alternative options

While identifying options we should be aware of the fact that there is a wide range of possible interventions or alternative options that can lead to accomplishing the objectives and settling the problem. The government should explore a broader range of alternatives, taking into account, first of all the easier, non-regulatory interventions that are usually less costly and may be more effective.

Lack of additional intervention

This option is also called “do nothing” or “status quo”.

According to RIA Methodology, this option should be mandatorily included in the RIA document. This option was described above, in the chapter on problem definition.

Information and Education

This type of option is designed to change the conduct of those involved in the public problem so that it can be settled. Examples of such options can be:

- Drafting and dissemination of voluntary guidelines on good practices in agricultural produce storage, packaging, and transportation.
- Information and education campaigns for the population on the importance of including fruits in the daily diet.
- Informing the population about the risk of food poisoning with bad quality agricultural products.

These actions may be sufficient and fast in settling the problem and would allow avoiding some interventions through a costly (especially for the business environment and the society), and time consuming regulation

Self-regulating

In some cases, self-regulatory measures, through which businesses agree to voluntarily reach a performance level desired by the government, could be cheaper and faster in accomplishing the objectives. Examples of options include:

- Certain agricultural producers could join in an association and establish certain requirements for the products of its members and issue specific marks confirming that the producers comply with respective standards. Promoting such marking among consumers, including on the export markets, makes it an important tool for accessing the market, insuring that the majority of producers will adhere to respective requirement to benefit from such marking. In such case, the government would avoid developing a costly regulation and allocating resources for surveillance and control.
- Some large companies could independently commit to reach the quality level desired by government to avoid the imposing of some mandatory regulation.

Co-regulation

Co-regulation is another solution by which the government could avoid imposing exaggerated costs on private sector through regulation, displaying trust in the solutions proposed by the business community that the government confers mandatory status. This solution could reach a higher compliance than the self-regulation option, at the same time avoiding to the maximum extent the exaggerated costs that would be imposed in case when the compliance requirements would be developed only by government.

An example of such option would be developing standards/requirements for products and processes by the private sector within a process coordinated by government, while subsequently, the government would approve these standards/requirements and confer them a mandatory status by including them in technical regulations or by referring to these standards in the regulations.

Market instruments (taxes, fees, permits, limitation in price and quantity, etc.)

Market instruments are designed to influence the conduct of market players by offering some negative or positive incentives.

- **Taxes and fees**, which discourage a certain behavior. For example, excises on certain products can reduce the demand for these products. Customs tariffs imposed on meat would reduce the imported quantity of meat, and, in this way, would insure higher sales on the local market for domestic meat producers.
- **Subsidies**, which are positive incentives. Thus, allocating subsidies per quantity of apples would stimulate the production of apples. Subsidies for exported domestic products would stimulate exports. Subsidies provided for land areas planted with more productive orchards and vineyards would stimulate the development of more competitive varieties and approaches in agriculture.
- **Improving access to financing**. Here we can include a number of tools provided by government, such as state guarantee of loans taken by agricultural producers, provision of grants for purchasing agricultural machinery, integral or partial coverage of interests on loans, allocation of budget funds for lending to agricultural sector, and others.

Adjusting the current normative framework

Even if the government intervention requires the involvement of regulation, we should examine in the first instance the current regulatory framework directly or indirectly regulating the undesirable situation (problem). If there are already regulations in place in this sense, it is preferable to use the latter rather than develop new acts. In this way, you will maintain the regulatory framework simple and transparent, and will avoid the risk of overlapping the current normative framework. The general trend is to try to consolidate the regulatory framework, thus improving its transparency and reducing or maintaining the costs for private sector the society as low as possible. An example in this sense could be the legislation codification, through which several regulations in one area are linked in on normative code/act (for example: Fiscal Code, Land Code, etc.). When drafting such option, one should take into consideration the principles of good regulation.

New regulation

Even in a case evidently requiring a new regulation there may exist several options that depend on the degree to which business is regulated. There are performance-based regulations and process-based regulation, situated at two regulatory extremes. To avoid imposing exaggerated costs for the business community, the government could regulate only the final result (performance) of the process. For example, the government could impose requirements for the quality of apples sold to final consumer, while how such quality is to be achieved would be left to the discretion of producers and vendors, the latter being free to choose the cheapest approach to production, storage, transportation, and market positioning of apples, under the condition that the final result (quality apples) is achieved. At the other extreme is the process based regulation, which imposes strict requirements to a part of or to the entire process through which apples are going or, in other words, to the entire life cycle of apples. Thus, the processes of apple growing,

storage, packaging and transportation could be strictly regulated. In this case, the government does not offer flexibility to producers and risks imposing costly, and even exaggerated requirements for accomplishing the desired result (quality apples) on them, which can lead even to the bankruptcy of many producers and limit the offer of regulated products.

Other variations of regulatory options can occur through implementation procedures, which can be insured only by government or can involve stakeholders from the private sector. Here we can include inspections, conformity certificates, laboratory expertise, and others, which can be carried out by state institutions or private institutions acknowledged by government. The involvement of private institutions could reduce the costs for the regulated private sector, because there will be a competition in providing such services, and the access to such services on the market will also improve due to the involvement of a larger number of institutions in service provision.

Regulations can also differ by the procedure for conformity insurance. In this sense, inspections, permits, conformity certificates, expertise testing, etc. can be involved. Ideally, one should avoid overlapping of conformity verification mechanisms, choosing the cheapest and most effective procedure to accomplish the objective.

Moreover, regulatory requirements should be focused on risks, so as to apply some mandatory procedures/requirements in situations when the risk is more imminent. For example, the risk to consumer health due to consumption of bad quality meat is higher at the stage of sausage processing than at the stage of selling sausages. Therefore, the risk-based sanitary and veterinary control would envision more inspections for sausage processing units, and fewer inspections for sausage trade marketing units.

Finally, when selecting and drafting regulatory options one should take into account the principles of good regulations described in this manual.

Combining options

Oftentimes, options can be combined, creating new options. Thus, regulatory options can be combined with information and education options, and/or market tools. A regulation could prescribe the requirements for production of apples, with regard to their safety; at the same time some provisions on subsidization of apple growers may be stipulated to stimulate the production of quality apples. This option can be combined with information and training campaigns on good apple production practices.

4.4.3 Identification of options in case of harmonization with the EU legislation

More civil servants believe that, in case of harmonization of the national legislation with the EU legislation, there are no options that can be taken into consideration, but one single option – harmonization option. However, particularly in cases of legislation harmonization it is important to develop a RIA and consider different options.

First of all, it is important to consider the “do nothing” option as a reference scenario to be able to differentiate and analyze the consequences of harmonization options. Further on, different EU

legislation implementation options should be examined, including transition periods, derogations, institutional arrangements, and imposing mechanisms. These options can be combined with technical and financial assistance that can be requested from donor institutions, especially from the EU. If we do not take into calculation the possible options, we are at risk of failing to transpose the EU legislation. The easiest form of failure would be a harmonized regulation remaining only on paper, without being observed by private sector or implementing government institutions due to the lack of capacities. The worst form of failure would be if the implementation of a regulation generates exaggerated costs for the society, leading to bankruptcy of many enterprises or of entire sectors.

Below are presented the specifics of harmonization options, confirmed through examples from other countries:

- **Negotiating technical assistance in the EU legislation implementation.** RIA allows us to understand how prepared are the private and public sectors to implement the European legislation, therefore it can serve as an evidence for negotiating the technical assistance in this sense. For example:
 - The Assistance Program for Central and East European countries (Phare) in implementing the Pre-Accession Strategy only within the period 2000-2006 provided for a budget of over 10 billion EUR.
 - Turkey benefits from approximately 90 million EUR only for the implementation of the Integrated Farmer Support Schemes Administration and Control System, harmonized with the EU system.
- **Negotiating the transition period and derogations.** Examples in this regard:
 - The majority of farmers and processing enterprises in Hungary were not prepared financially to implement the EU veterinary and phytosanitary standards. The solution was as follows: they were allowed to apply the existing technologies several years following the accession, but only for the domestic market.
 - Large quantities of quality wine in Hungary used to be bottled in 1 liter containers, which were not complying with the EU standards at the moment of accession. The impact assessment demonstrated that neither the limitation of wine only to domestic market, nor its re-bottling in standard bottles was acceptable, because a big part of the sector would have gone bankrupt in both cases. The solution was allowing trading of existing wine on the EU market, but prohibiting wine bottling in 1 liter containers for the future.
 - At the moment of accession, approximately $\frac{3}{4}$ of the Hungarian consumers preferred milk containing 2.8% of fat in it, while in the EU, only two types of milk were allowed: containing 0-1.8% of fat – called skimmed milk, and containing no less than 3.5% fat – called whole milk. The implementation of this provision would cause a shock for the population, affecting especially the vulnerable categories. For a family with two children, the cost of this provision would have constituted approximately 1% of their budget. The initial solution was postponing the implementation of this regulation by 5 years. However, after 5 years following the accession, Hungary, jointly with other new members convinced the EU to amend this regulation. Thus, milk with a fat content ranging between the two initial limits is nowadays allowed for sale in the EU.

- Greece obtained introduction of cotton in the support scheme (subsidization) for agricultural crops at the moment of joining the EU. At that moment, cotton was not so important in the EU, contributing only with 0.15% to the gross agricultural product, but having a high regional significance. This can be seen from data of 2005, when Greece used to produce approximately 76% of the cotton grown in the EU, which constituted approximately 9% of the gross agricultural product of Greece. Cotton was grown on circa 380,000 hectares, with 79,700 farmers involved in cotton cultivation in Greece. Thus, had it not been included in the support scheme, a large part of the population, as well as the Greek economy would have been affected after accessing EU.
- EU Directive on content of nitrogen originating from natural fertilizers in the soil (91/676/EEC) allows for derogations, if these are justified. The United Kingdom obtained the permission to have a maximum level of 250 kg of nitrogen/ha versus 150 kg/ha generally regulated, which represents significant savings for the British agriculture.

4.5 ASSESSING THE IMPACTS AND COMPARING OPTIONS

When the options have been identified, their impacts are analyzed and compared in order to recommend the most favorable option. This chapter combines the two RIA elements – impact assessment and comparing options, because they are closely linked and cannot be easily explained separately. Although in the RIA document the comparison of options follows after the analysis of impacts, this chapter starts with the decision making criteria that are the basis for comparing options in order to understand their need, and then continuing with analytical methods supporting the criteria, and finally explaining how the impacts are identified and analyzed.

The key quality criteria in analyzing the impacts:

- For each option, the main costs and benefits shall be described, including the economic, social, and environment related ones, confirmed by evidence.
- Impacts shall be quantified to the extent possible. Proportionality principle shall be also applied, which means the preliminary RIA requires less quantification compared to final RIA, or less important impacts require less quantification than more important ones.
- If the impacts are not quantified, they shall be assessed from the quality point of view.
- RIA shall assess only the additional costs and benefits compared to the situation in which no additional action would be taken, i.e. compared to the “do nothing” option.
- RIA shall analyze separately, if necessary, some specific impacts (impacts on fundamental rights, SMEs, competition, etc.).

The key quality criteria in comparing and recommending options are:

- RIA shall present a summary of positive and negative economic, social, and environmental impacts for the analyzed options.
- The benefits of proposed options shall justify their costs. This criterion might not be applicable in cases related harmonization with EU legislation or other similar cases, when certain actions are taken even if these generate higher costs than benefits. In such cases the “do nothing” option is not a feasible one, being used only as a reference/base scenario for calculating the impacts.
- The recommended option shall generate higher net benefits and shall be more effective in accomplishing the objectives compared to other options. The proportionality principle will be

applied, meaning that preliminary RIA requires less quantification compared to final RIA or less important impacts require less quantification, options being compared on basis of a more qualitative presentation of impacts.

4.5.1 Decision making criteria

RIA analyzes the impacts of options and compares them in order to inform the decision making. Options are compared for identifying the best option. The key decision making criteria in selecting the preferred option are as follows:

- Government option/intervention is acceptable if its results (benefits) are worth the effort (costs), otherwise the option would bring higher costs rather than benefits. If for several options the benefits are higher than the costs, the recommended option is the one generating higher net benefits. However, this criterion might not be applicable in cases of harmonization with EU legislation or other similar cases, when certain actions should be taken even if they generate higher costs than benefits. In cases related to harmonization with the EU legislation, RIA can help identifying the cheapest approach to implementing the EU legislation by applying the decision making criterion presented below.
- The government should find the cheapest option for resolving the problem. This decision making criterion is oftentimes used in combination with the first criterion, and is designed to narrow the set of recommended options. The given criterion can be used separately in cases when the intervention is imposed by the situation, like in the case of legislation harmonization, but there are still several options out of which the cheapest one should be selected.

To meet the above described selection criteria we must identify and analyze the impacts (benefits and costs) of options. RIA should analyze the impacts as net changes compared to the “do nothing” option, which is used as a reference/base scenario. It is required to show how each option differs/deviates from the base scenario, in both positive and negative aspects. The impacts must be quantified to the extent possible, taking into account the fact that the more you quantify the impacts, the more convincing the analysis.

4.5.2 Analytical methods for analyzing the impacts and comparing options

The following two analytical methods are used to meet the above mentioned two decision making criteria in selecting the recommended option: cost/benefit analysis, and cost/effectiveness analysis.

Cost-Benefit Analysis (CBA)

The following formula is applied for this analysis:

Benefits – Costs = Net Benefits

All the negative and positive impacts are compared by this formula to respond to the question if the options can be considered and if the latter produce more benefits than costs.

The cost-benefit analysis (CBA) is probably the most famous technique for analyzing public policies, widely used in RIA development. The CBA is comprised of three main steps. The first step includes identifying the potential impacts (benefits and costs). The benefits and costs are identified as explained in the section on identifying impacts bellow. The second step includes evaluation of identified costs and benefits so that different impacts can be combined in order to offer an aggregate evaluation of total benefits and total costs, as explained in the respective chapter bellow. The third step involves distribution of benefits and costs over a period of time. Benefits and costs which sometimes emerge in the future are less valuable than those recorded currently, and an updating procedure is used to convert the impact recorded in different periods of time into equivalent values that can be combined.

It is important to mention that, although, theoretically, this method assumes that the costs and benefits are quantified and expressed in monetary units, in practice it is applied in case of a combined analysis between the quantified data and those analyzed from a more qualitative perspective, including in a narrative form. In such situations, the given method is also called “partial cost-benefit analysis”. Such approach is sufficient as long as it allows comparing the costs and benefits to determine the extent to which the benefits justify the costs and which option is generating higher net benefits. In the easiest form, this approach looks like a comparison of advantages and disadvantages, as required in the preliminary RIA. Examples of such approaches are presented in the chapter on comparing options.

Keeping in mind that this is a universal method, the following chapters are structured according to the CBA steps and contain examples for a better understanding of this method.

Cost-effectiveness analysis (CEA)

For this analysis, one of the following formulas can be applied:

1. $CEA = \text{Costs} / \text{Benefits}$. This formula determines how many lei should be spent to generate one lei of benefits. It can be applied when it is possible to quantify the benefits of an option in monetary units.
2. $CEA = \text{Costs} / \text{Effects (saved lives, etc.)}$. This formula determines how many lei should be spent for obtaining one benefit unit, which is expressed in some natural units. It can be applied when the benefits cannot be easily expressed in monetary units, but can be determined in natural units, such as the number of saved lives, number of cleaned hectares, etc.
3. $CEA = \text{Total costs} / \text{total effects (usually the objectives of the option)}$. This formula determines the total cost of implementing an option that generates a certain quantity of benefits. It is used in cases when a rigid objective is set, which must be achieved. Therefore, only options accomplishing the total objective will be analyzed, the cost being the only varying factor.

This method responds to the question: what kind of actions (option) must be undertaken to maximize the results or what option is cheaper in accomplishing the objectives?

Presented below is an example of cost-effectiveness analysis, which analyzes different options for anti-hail protection of agricultural land

	Total costs of the option, in lei	Number of hectares protected from hail	Costs per protected hectare, in lei
Option 1	4 000 000	12 000	333
Option 2	5 000 000	18 000	278
Option 3	7 000 000	20 000	350

In this case, option 2 is the most cost-effective one, because it generates a benefit unit with the lowest costs. However, in such cases, we need to see if the analyzed options generate acceptable total benefits, because it might happen that a more cost-efficient option generate several times less benefits than a less effective option, and could not be acceptable.

4.5.3 Identifying impacts

Impacts can be analyzed by two dimensions: by types of impacts and by characteristics of impacts.

Types of impacts

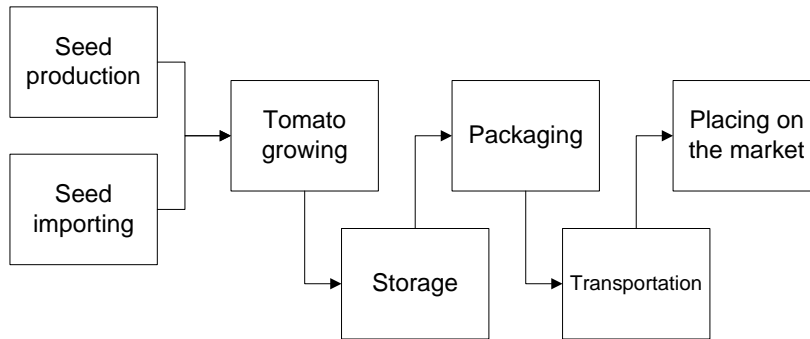
Traditionally, public authorities have been more concerned with the budget impacts of the proposed options. This resulted in drafting some policies/regulations considered almost “free of charge” by civil servants, which means interventions involving no significant costs for the public budget. In essence, the authorities would transfer the costs to external interested parties, i.e. to the businesses and the society, in general. For example, introducing a permit for which payments were charged to the beneficiaries, who covered all the costs associated with their issuance, including for examining the application, carrying out site inspections, and analyzing product samples in the laboratory. As a result, this led to an inflation of regulations that imposed exaggerated and unjustified costs, creating a need for analyzing a broader spectrum of impacts, and not only of the budget ones, based on which the options should be compared.

In order to understand the entire range of potential impacts and assess the cumulative impacts for the entire society, RIA divides all the impacts into three main groups:

1. **Economic impacts.** These are the impacts on:
 - competition;
 - competitiveness, trade and investment flows;
 - agricultural production;
 - operational and business unfolding costs;
 - business administration costs;

- SMEs;
- public budget and budgets of public authorities;
- ownership rights;
- innovations and researches;
- consumers and household budgets, in terms of quality and price of products and services, and incomes of the population;
- certain regions and sectors;
- macroeconomic indicators;
- etc.

In agriculture, it is important to keep in mind the value chain or the life cycle of agricultural products in order to understand the entire spectrum of potential impacts and avoid omitting some impacts that could affect the competitiveness of products. A simplified example of value chain for tomatoes is presented below:



Thus, we need to identify if the proposed solution could have a direct or indirect impact on any section (element) of the value chain.

2. **Social impacts.** These are the impacts on:
 - employment and labor market;
 - standards and rights related to work place quality;
 - social inclusion and protection of certain social groups;
 - gender equality, non-discriminatory treatment;
 - private life, family and personal data;
 - access to public services, including to justice, education;
 - public health;
 - security, criminality;
 - etc.
3. **Environmental impacts.** These include the impacts on:
 - climate;
 - energy transportation and use;
 - air quality;
 - biodiversity, flora, fauna;
 - water quality and quantity;

- soil quality and area available for agriculture;
- land use;
- waste generation and recycling;
- etc.

Characteristics of impacts

The above described impacts can have different characteristics:

Impacts can be positive (benefits) or negative (costs)

Benefits can be gains or losses restored. Examples of gains include: additional revenues generated for the budget or businesses; additional subsidies for farmers. Examples of losses restored are: reducing the bureaucratic costs for farmers through elimination of some licenses; reducing the losses for farmers through extension of anti-hail system, etc.

Costs can be losses or gains forgone. Examples of losses include: administrative costs imposed through introduction of a new certificate for certain agricultural products; introduction of requirements for cold storages for agricultural products that involve additional costs for adjusting and maintaining the cold storages in compliance with the new requirements. Examples of gains forgone: reducing the incomes planned by farmers through cancellation of subsidies in agriculture; reducing the budget revenues through exclusion of some licensing fees; as a result of the intervention, reducing the sales of agricultural enterprises, which would have taking place in case of base scenario (“do nothing” option).

Example from RIA to the UK regulation on implementing Directive 2007/43/CE of the European Council of 28 June 2007 on Establishing Minimal Standards for Protection of Chicken Kept for Meat Production

Potential Directive implementation costs:

- investment costs;
- operational costs;
- training costs;
- administrative costs for the producers;
- costs for public sector: information, inspection, enforcement;
- negligible environmental costs not quantified.

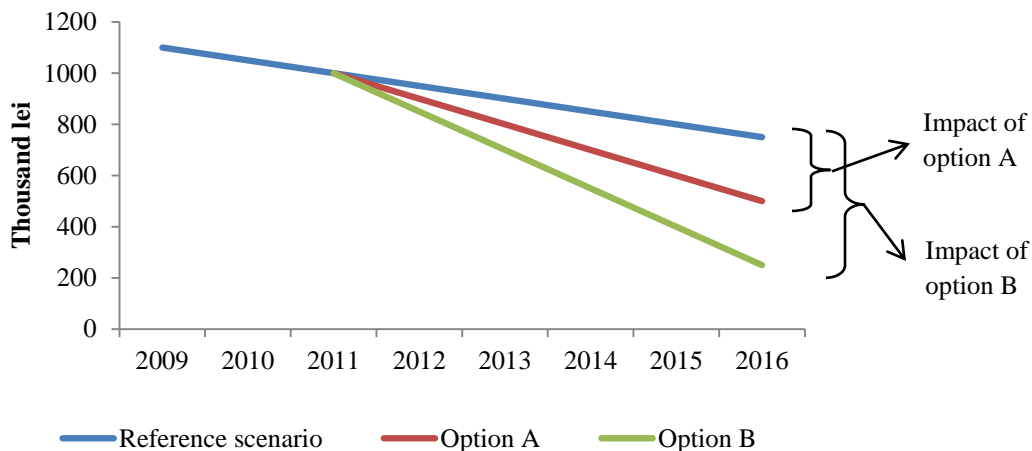
Potential benefits from Directive implementation:

- Chickens’ welfare, reflected through:
 - Reducing stocking density;
 - Reducing footpad lesions;
 - Increased ventilation;
 - Increased period of darkness.
 -
- Finally, the chickens’ welfare turns into a public good, because the high stocking density, stress, etc., typical for the broilers can cause the appearance and spreading of diseases, including highly pathogenic avian influenza, with implications on public health.

While presenting the impacts of options, RIA must assess the impacts as net changes compared to the “do nothing” option (reference scenario), also called incremental or marginal costs and benefits (changes in or deviations from the reference scenario). RIA must demonstrate how each option differs from the base scenario in terms of impacts (benefits and costs). Upon assessing the impacts, we need to take into account the risk or probability of their appearance, which fact can affect the quantity/value of impacts.

To help better understand how impacts occur, we’ve included an example of benefit in graphic form below.

Example: the costs associated with mandatory certification of agricultural produce are constantly decreasing, due to the competition on the certification services market and laboratory tests. However, there are options that could reduce these costs even more, and namely option A and B. The effect (benefit) of these two options is graphically presented below. The benefit is calculated as deviation from the reference scenario or as area between the reference scenario line and option line, as presented in the graphic.



Impacts can be big and small (principle of proportionality)

As mentioned in the beginning of this document, particularly in the section on impact assessment, the principle of proportionality is applied, i.e. the focus should be put on relatively big impacts (impacts affecting more people, more important sectors, etc.). The more significant the impacts, the more detailed their assessment should be. Small impacts which do not affect the comparison of options significantly can be only mentioned, without significant quantification.

Moreover, impact assessment is not a scientific process, the authors being restricted in time, resources, and data. Therefore, high accuracy in assessing the impacts is not required. Their analysis is carried out up to the point when it is sufficient to determine if the impacts are bigger than the costs and which option generates higher net impacts and is cheaper. Whenever it is impossible to estimate the value of impacts accurately, one could operate with the intervals within which their value fits.

Distribution of impacts in time

Another important characteristic of impacts is their distribution in time. Thus, impacts can be:

- one-time, for example, investments in administrative capacities, which take place at the beginning of an option implementation,
- short-term, related to a temporary phenomenon, such as allocation of subsidies to farmers within a program approved for fixed period of time,
- long-term or permanent, for example, costs for observing some apple quality requirements in compliance with the provisions of a regulations that has no expiry term.

If the in-time impact distribution is not taken into account, the RIA authors risk recommending an option that implies higher costs than benefits for the society. For example, if the analysis is carried out only for the first year of implementation, it might happen that the option will be recommended, the analysis suggesting that the option generates net benefits, i.e. the benefits are higher than the costs. However, if these are only one-time benefits, i.e. take place only in the first year of implementation, while the costs are permanent, the one-year only based analysis would not be representative, favoring the benefits part, while the analysis for a longer term, let's say for 5-10 years would show a more realistic situation, in which the cumulative costs might exceed the one-time benefit. Thus, even in the case of carrying out a less quantified analysis, one should take into calculation the distribution of impacts in time. If, however, the impacts are uniformly distributed in time, it might be sufficient to carry out an analysis only based on one representative year, when the intervention achieved its maximum capacity, and this might be sufficient for us to answer the question if total benefits are higher than the costs. More details about the analysis of impacts in time are provided in the chapter on quantification of impacts.

Administrative costs

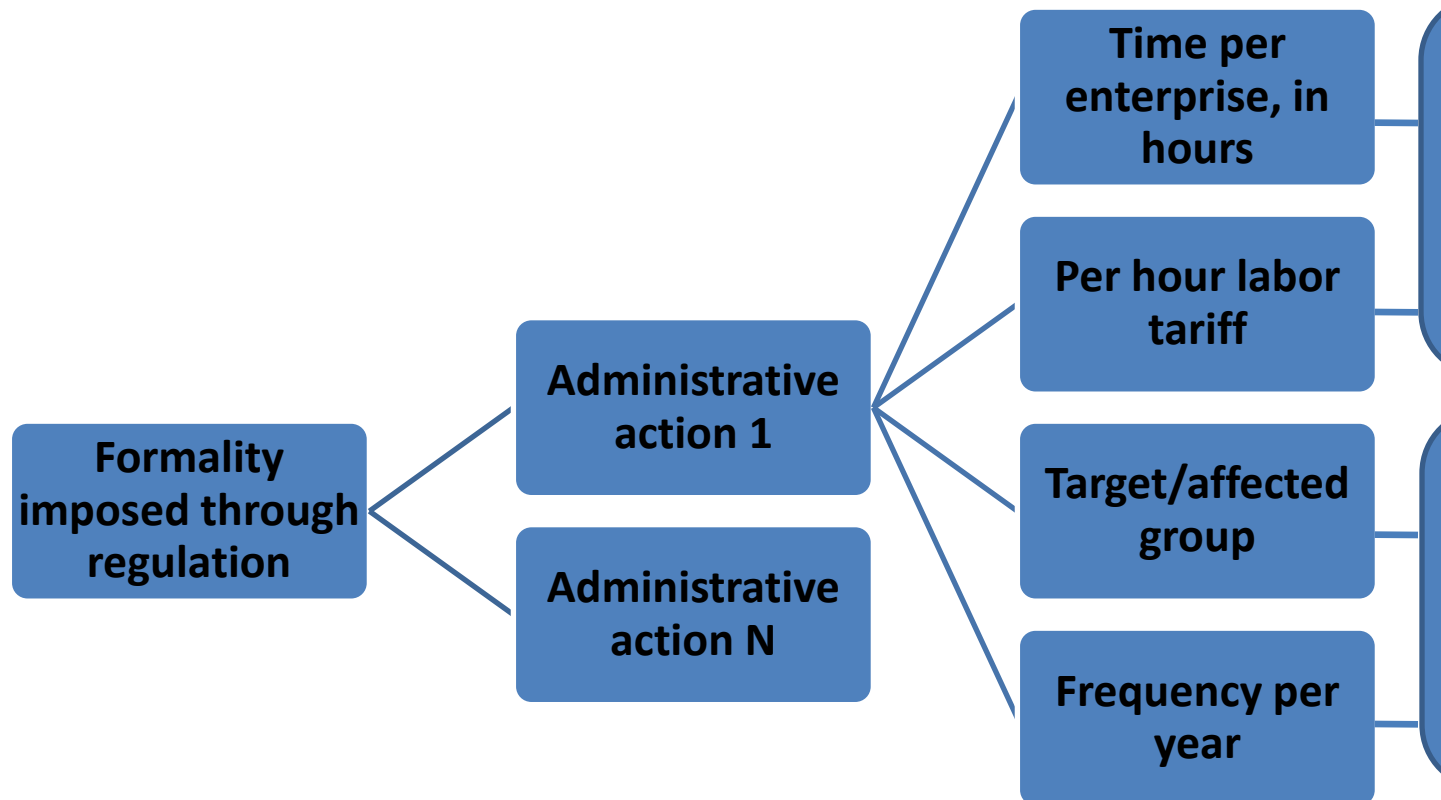
As RIA relates to government intervention, it is important to take into account the administrative impacts that the government might impose, which could mean increased costs and risks for businesses and diminished competitiveness for the private sector. Keeping in mind the already mentioned good regulation principles, we should insure that the proposed option does not generate exaggerated and unjustified administrative costs.

We can calculate the government imposed administrative costs based on “Standard Cost Model” (SCM) analysis, widely applied in many countries, which looks as follows:

$$\text{Administrative costs} = P \times Q,$$

where P is the price/cost of imposed administrative actions, and Q is the number of administrative procedures per year.

The details of administrative costs calculation can be schematically presented as follows:



This approach was used in calculating the benefits brought by the so-called “Guillotine 2+”, which included a package of laws designed to reduce the costs of permits in the Republic of Moldova. Thus, according to calculations, “Guillotine 2+” is to eliminate circa 100 permits, and, as a result, to produce benefits in form of savings for the private sector in the amount of over 27 million lei annually. To estimate the savings, the direct costs for obtaining permits, planned to be eliminated, such as the official tariff, costs associated with collection and preparation of documents to be attached to the request, including the remunerated time of employees, and travel costs to the institutions issuing respective documents and permits incurred by entrepreneurs in the previous year were calculated. These costs were multiplied by the total number of permits issued in the previous year in order to calculate the total value of administrative costs which were to be saved as a result of reforms.

Distributed and specific impacts

RIA should also determine if it is necessary to separately examine some specific impacts (impacts on fundamental rights, SMEs, competition, etc.). Even if an option generates net benefits (positive difference between total benefits and total costs), it can have disproportionate effects on some groups of the society or some sectors of the economy. This is why it is also important to mention if such impacts are possible, and assess if these could be significant.

In this regard, we can distinguish two types of distributive effects, which are worth being explored:

- **Impacts on different social and economic groups.** Identifying the ‘winners’ and ‘losers’ in case of an intervention help us anticipate the obstacles to implementing the option and can indicate the need for changing the design of the intervention in order to reduce the negative effects. For example, a proposal can be beneficial for consumers, while seriously affecting another economic sector, and having negative effects in the long run. The effect can be distributive even within the same sector. For example, imposing some restrictions on vehicles for transporting agricultural products could facilitate the large companies possessing adequate vehicles, but could lead to bankruptcy of the majority of SMEs that cannot afford to invest in new vehicles. Therefore, large enterprises would benefit from increased sales of transportation services of agricultural products at the expense of market loss by SMEs.
- **Impacts on existing inequalities.** We should also compare the impacts on vulnerable groups or different regions in order to understand if the options could preserve the existing inequalities unchanged, worsen or improve them. In this way, even if the recommended option generates net benefits, we should make sure that we will not cause new inequalities in the society. If an option suggests introducing new subsidies, we should make sure that no agricultural producers will be disfavored in accessing such subsidies.

The distributive character of impacts is important in the cost/benefit analysis, because it can lead to double adding of impacts. For example, the option imposing restrictions on the quality of apples reduces the sales volume of apples. It would be wrong to add to costs the sales reduction value at producers, distributors, wholesalers, and stores, because, in this case we would add several times the same effect distributed within the value chain of apples, as in the end, only one sales value reduction has taken place, reflected throughout the entire value chain. These transfer effects should be identified and explained separately, avoiding the double adding of these while calculating the total impacts for the CBA.

4.5.4 Quantification and in-time distribution of impacts

Quantification of impacts

Impacts must be quantified to the extent possible. The more they are quantified, the more credible and convincing the analysis becomes. In this case, there is more information/evidence for making a good/quality decision, helping the decision makers to compare the options. Impacts can be quantified in natural units – kilograms, meters, units, etc. Impacts should be estimated, to the extent possible, in the same unit of measure in order to be able to add and compare them. When quantifying the impacts, we must take into account the risk or probability for its appearance, which can affect the quantity/value of impacts.

The most advanced level of quantifying impacts is their evaluation in monetary units, which is also called “market evaluation” or “economic evaluation”. However, in some cases, this is not easy to do, especially for social and environmental impacts, which are represented by goods that are not traded on the market, and have not market value, respectively. In such cases, we could

estimate the “willingness to pay” or the “willingness to accept compensation” by the stakeholders/population for such goods.

Example from RIA to the UK regulation on implementing Directive 2007/43/CE of the European Council of 28 June 2007 on Establishing Minimum Standards for Protection of Chickens Kept for Meat.

It was difficult to evaluate the potential benefits identified as a result of implementing the Directive, as the latter considered the welfare of chickens, which was to finally turn into a public good, reducing the risk for the health of the population of spreading diseases among chickens. To estimate the population’s ‘willingness to pay’ for such goods, a survey was organized, during which the population was asked how much they would agree to pay annually, in the form of some tax, for a certain level of chickens’ welfare, and therefore, for a reduced risk to the consumers. The amount indicated by respondents was extrapolated so as to estimate the value of benefits.

In cases when impacts cannot be quantified or it is too difficult to do it because of the lack of time, resources and data, or based on proportionality principle, this fact must be explained. In such case, the impacts could be analyzed in a qualitative manner to allow comparing the options, specifying, for example, how many people could be affected, what kind of people could be affected, such as vulnerable categories, etc. The given effects can be characterized as ‘small’, ‘medium’ or ‘big’ for comparing and analyzing the impacts.

Example of qualitative analysis of impacts (Impact assessment for reviewing the cotton sector support schemes, developed by the European Commission): Environmental impacts of alternative crops on cotton.

	Relative impact on			
	Water quality	Water quantity	Soil	Biodiversity
Non-irrigated crops	☺☺	☺☺☺	☺☺	☺☺
Irrigated crops	☺☺ – ☺☺☺	☹☹ – ☺	☺☺ – ☺☺☺	☺☺ – ☺☺☺
Corn	☹	0 – ☹☹	0 – ☺	0 – ☺
Vegetables	0 – ☹☹	0 – ☹☹	0 – ☹☹	0 – ☹☹
Cotton	Reference			

In this case, cotton was used as a reference scenario, while the impacts represent deviations from this scenario, i.e. cases in which cotton cultivation would be substituted by growing other crops, as a result of offered incentives. Relative environmental impacts, where ☺ means relatively

small positive impact, ☺☺☺ – relatively big positive impact, 0 – neutral impact, while ☹ means relatively small negative impact, ☹☹☹ – relatively big negative impact.

It is important to mention that, in case of a more qualitative evaluation, the approach and method according to which the analysis was carried out is clearly explained in RIA.

Evaluation of in-time distributed impacts

When the impacts have been identified and quantified, and if these are unevenly distributed in time, as explained in the characteristics of in-time distributed impacts, one should try to calculate the impact flow in monetary units. This is done through annual recording of benefits and costs for the entire validity term of the intervention, or if the intervention has not pre-established timeline – for a reasonable time which would allow discovering the uneven distribution of impacts in time. From the experience of other countries, a period of 5 to 10 years of analysis is recommended. The difference between annual benefits and costs is calculated for each year of this period, calculating the net cash flow that can be in form net benefits or net losses.

The money collected later on in time has a lower value than the money collected instantly. This is explained by the fact that the money collected in the future represents an opportunity cost in terms of income that that could be earned by investing the funds in a savings account that brings interest or in a production activity that brings income. This is the reason why persons taking loans should compensate to the creditor for the income that the latter refrains from, by paying an interest rate.

To combine the annual cash flow net value into an aggregate figure, this value should be converted in equivalent terms. This is done through a discounting process that transforms the future values into a present time equivalent value. This important process can be explained through a simple example. Imagine that a firm or a person is asked to choose between being provided the amount of \$100 today and \$100 next year. The choice will be in favor of \$100 provided today, which could be subsequently deposited into a savings account, gaining, let's say, 10% annually. After one year of being paid the interest, the balance of the deposit account will increase, constituting \$110. The perspective of obtaining \$100 one year later is equivalent only to \$100 divided to 1.1 = \$90.9 under the present period conditions. This process of future value reduction to a present equivalent value is called discounting. For example, if this procedure extends over another year, then we should admit that the interest will be also obtained on the interest for the past period, thus increasing the savings balance to \$121 (\$110 + \$11). The payment of \$100 in two years will be discounted, providing a net value of \$100 divided to 1.21 = \$82.6. A general presentation of the net present value calculation (NPV) is as follows:

$$NPV = \sum_{t=0}^n \frac{Bt - Ct}{(1+i)^t},$$

Where Bt and Ct are benefits (incomes) and costs (expenditure) from year t , i is the discount rate (interest rate), and n is the project period.

The part of the formula adjusting the value of impacts to the present value is called discount factor, which looks as follows:

$$\frac{1}{(1+i)^t}$$

The Ex-Ante Guidelines developed by the State Chancellery recommends using for Moldova a base interest rate set by the National Bank of Moldova as a discount rate (7%).

It is easy to calculate the NPV using discounting tables, where discount factors are already calculated for different discount rates and years, and must be only multiplied by the net flows value for each year.

The criterion for selecting the option based on NPV proceeds directly from those already discussed above, and namely, that an option is worth being recommended if the NPV is positive. Presented below is an example of applying discounting in assessing the impacts of a 4-year period option.

Year	0	1	2	3	4
Benefits	0	0	0	1500	1500
Costs	1500	300	300	300	300
Net benefits	-1500	-300	-300	1200	1200
Discount factor (10% rate)	1,000	0,909	0,826	0,751	0,683
Net Present Value (discounted)	-1500	-273	-248	901	820

If simply calculate the net benefits, we would obtain the following: net cumulative benefits = – 1500 – 300 – 300 + 1200 + 1200 = 300. Thus, the option would pass the test, which states that the benefits must be higher than the costs. However, if we apply discounting, we get NPV = – 1500 – 273 – 248 + 901 + 820 = – 300. In this case, the analyzed option failed the test. This example shows us how non-inclusion in the calculation of money value/impacts in time can induce the decision on selecting the option for government intervention.

4.5.5 Comparing and recommending options

Following the analysis of the impacts described above, RIA shall hence provide a summary of both positive and negative economic, social and environmental impacts for each of the analyzed options. As a rule, the summary of economic, social and environmental impacts of all options is presented in form of a Table. This table allows having an easier analysis of all the options to be used in the process of consultations with relevant stakeholders and decision-makers.

Benefits can then be provided in both quantitative and narrative form as described in the chapter assessing and quantifying all the impacts.

An example of quantitative and qualitative assessment of the impacts is presented below. The impact analysis of the Regulation on establishment of an administrative integrated and control

system and of a land parcel identification system in Turkey was developed by the Ministry of Agriculture and Rural Affairs from Turkey in 2009. The systems proposed in the given Regulation are aimed to optimize the process of subsidy allocation to farmers.

Impacts	Option 2. (million EURO)
Cost-benefit analysis (quantified assessment)	
- Present value of benefits (for a period of 9 years)	538.6
- Present value of costs (for a period of 9 years)	50.0
- Present value of net benefits (for a period of 9 years)	488.6
Other impacts (qualitative analysis)	
- Environmental impact (effects)	positive
- Social impact (effects)	positive
- Impact on administrative burden for farmers	positive
- Impact on competition	positive
- Impact on EU approximation process	positive

The aforementioned Regulation was recommended following the given analysis since the assessment showed that the new system will generate more benefits than costs. More details on the calculations used for the given RIA can be found in Annex 2.

An example of an impact assessment presented in a monetized form is taken from the United Kingdom RIA carried out with regard to public health aspects of the Anti-Smoking Law, which also affects the tobacco industry, and can be seen below.

Annual benefits, million £	Option 1	Option 2	Option 3	Option 4
a) Number of deaths among passive smokers	75	350	0-350	150 -250
d) Savings for the national health system	20	100	0-100	40-100
...
Total benefits	1289-1371	3374-3784	0-3784	2842-3616
Annual costs, million £				
j) Enforcement	-	5-13	0-20+	7-20
l) Losses to the budget from reduction in excise collections	428	859	0-859	859
m) Losses incurred by the tobacco industry from smoke abandonment	43	97	0-97	86-97
...
Total costs	766	1660-1668	0-1674	1538-1675

Net benefits	523-605	1714-2116	0-2110	1304-1941
--------------	---------	-----------	--------	-----------

Since it was considered that the given effects have shown a relatively even distribution in time, the analysis was conducted for a period of one year only. This example shows once again that emphasis shall be put on the main impacts and a lower degree of precision (use of larger intervals for impact analysis) enables to make a comparison and identify the most favorable option to reach the expected outcome.

An example showing the quantifiable impacts calculated in natural units combined with a qualitative analysis can be found in RIA for the Council Recommendation Proposal on smoke-free areas conducted by the European Commission. The below example shows only a part of the social impacts generated through the implementation of the given proposal.

	Baseline level	Policy 1	Policy 2/ Policy 3	Policy 3+/ Policy 4
Social impact				
Reduction in annual mortality caused through exposure to secondary smoking	6 007	-386	-774	Ranging between -774 and -1 550
Reduction in morbidity degree caused by secondary smoking exposure		+	++	+++
Drop in mortality through reduction of active smoking		+	++	+++

It is easier to quantify mortality drop since the latter is expressed in number of persons. However, it is more difficult to calculate reduction in morbidity level since this estimation is based on a large spectrum of various diseases caused by this phenomenon. Therefore, this indicator is analyzed more from a qualitative point of view.

An example solely based on qualitative analysis of all options can be found in the Impact Analysis of the draft European Directive on sale of planting materials for fruit growing developed by the European Commission.

	Impacts						
	Administrative impacts on suppliers	Technical impacts on suppliers	Impact on the users of the planting material	Impact on final consumers	Market transparency	Employment	Environment
Cancellation of the existing legislation	- +	+	- - +	- -	- - -	- +	-
No changes (status quo)	0	0	-	-	- -	0	-
Self-regulation	- +	- +	- +	-	- - +	- +	-
Simplifying	- + +	- + +	- + + +	+	+ + +	+	+ +

the existing legislation							
--------------------------	--	--	--	--	--	--	--

Note: – = costs, + = benefits, 0 = no changes

4.6 IMPLEMENTATION AND MONITORING

The main quality criteria assessed in the implementation and monitoring chapter are the following:

- RIA shall include an implementation plan stipulating the deadline by which the Regulation underpinning the recommended option shall enter into force;
- RIA shall describe how the proposed option will be monitored and evaluated once implementation begins, and shall specify the respective performance indicators.

Implementation

Failure to ensure proper implementation can lead to unsuccessful delivery of the regulatory acts. For instance, when implementation of the proposed option is not sufficiently planned, it might appear difficult to deliver on it, and therefore the provisions of an eventual regulation included in the option might remain only on paper or might generate considerable unforeseen costs for the society.

Therefore, RIA shall provide a detailed description of the implementation process for the given option, or in more complex cases it shall include an implementation plan and explain how it will be put into action. To this end, it is important to estimate the financial cost of enforcement and concurrently to clearly determine the current capacities of the public administration authorities responsible for the implementation of the given regulatory act and other actions necessary to encourage attraction of other additional investments if needed with a view of ensuring a more efficient and effective implementation of the proposed option. In case of insufficiency of resources and existing infrastructure, it is important to estimate what needs to be changed or improved to ensure a more successful implementation of the proposed scenario.

The final impact analysis of the regulatory act shall suggest and justify the date when the given regulation shall come into force, as well as shall substantiate the validity term proposed for such actions (provided there is a time and place-binding frame for the given legal provision). It is extremely important to analyze the term of its entering into force which shall be correlated with a proper analysis of the existing implementation capacities, expected impact of the regulatory act and the general nature of the selected option. It shall be highlighted that many times when the regulatory acts are envisaged to enter into force in a too limited period of time, they might appear totally inefficient and unenforceable and a number of entities will not be ready to ensure compliance with the new regulations, whereas the state bodies will not have sufficient time to harmonize the previous regulations with the new regulations.

Monitoring

Monitoring is the last element in the RIA process. RIA authors shall be able to verify if implementation of the recommended option is conducted according to the scheduled plan and to

what extent it meets the established objectives. If the recommended option fails to reach its objectives, it shall be evaluated if the given failure is the result of mistakes in RIA development or due to improper implementation. It might happen that the problem was not defined correctly, objectives were not set up realistically, or implementation was the responsibility of some institutions that lack sufficient capacities to understand the proposed option or are reluctant to contribute to its timely implementation, etc. This evaluation of the causes of failure will enable RIA authors to decide if some corrective actions are necessary to be introduced in the process of implementing the given option.

The monitoring procedure requiring the use of appropriate performance indicators will provide valuable data and evidence in this regard. Therefore, RIA shall provide a full description of such monitoring and evaluation procedures, and define the core indicators linked to the main objectives of the given proposal. These indicators shall serve a clearly defined goal, i.e. shall estimate to what extent the suggested intervention was delivered upon and the set-up objectives reached. Another important factor in choosing such indicators is how easy reliable data for such monitoring can be collected. The cost of collecting relevant data shall not be higher than the value of the information disclosed by it. Similar to objectives, performance indicators shall also be SMART. For more details, see the chapter on setting-up objectives from this Manual.

RIA authors can also provide for monitoring according to the recent Methodology on monitoring the legislation implementation process approved through the Government Resolution No. 1181 of 22.12.2010.

5 RIA DOCUMENT

RIA document can be done in form of preliminary RIA or final RIA. Preliminary RIA shall be carried out by relevant authorities prior to drafting a regulatory act. However, final RIA is prepared only upon the decision of the Working Group for Regulating Entrepreneurial Activity or RIA's authors. Final RIA is done on the basis of preliminary RIA and it might include additions to the existing chapters or be updated with new chapters. When developing RIA documents, it is recommended to take into account the quality criteria of RIA analysis, whose summary is presented in Annex 1 and the relevant chapters from RIA Manual.

The structure of documents presented in this chapter is correlated to the existing RIA methodology requirements. As it was mentioned in the introduction to this Manual, the Methodology is currently going through a revision process and might be changed, which will inevitably generate the need to change this chapter whereas the chapters related to RIA elements developed on the basis of good international practices will remain valid.

Preliminary RIA document

Preliminary regulatory impact assessment contains the following chapters:

A. Problem definition. Preliminary regulatory impact assessment shall identify the problem that needs to be resolved and establish the desired outcomes to be achieved by the state as a result of the given regulation. Problem definition shall contain the following elements:

- legal element stipulating how the given problem is reported to a given public authority responsible for the state intervention;
- analytical element explaining what caused the occurrence of the given problem and estimating its magnitude;
- evaluation of possible consequences in case of status quo scenario;
- setting up the rationale for the state intervention.

While describing these elements, it is recommended to consult the chapter on problem definition and setting up objectives from this Manual.

B. Major costs and benefits expected from the state intervention. The preliminary regulatory impact assessment helps identify major possible quantitative and qualitative effects of the state intervention. These impacts will be grouped in the following way:

- negative impacts or costs of the state intervention;
- positive impacts or benefits of the state intervention;
- major uncertainties generated by the potential impacts of the state intervention.

When describing these elements, it is recommended to consult the chapter on impact analysis and comparison of options from this Manual.

C. Evaluation of alternative approaches. Preliminary regulatory impact assessment includes at least two alternative approaches that need to be taken into account in trying to address the identified problem. A mandatory alternative is the “do nothing” option. The other alternative options shall be construed on the basis of the existing needs, such as:

- adjusting some existing regulations;
- changing the implementation mechanism of some existing regulations;
- educational and information campaigns;
- individual (self-regulation) regulation;
- individual or third-party regulation;
- market instruments, including taxes.

The given options shall be presented using the following Table:

Alternative options	Possible advantages	Possible disadvantages
Do Nothing		

In describing these elements, it is recommended to consult the chapter on identification of options and analysis of impacts and comparison of options from this Manual.

D. Consultation strategy. Preliminary regulatory impact analysis identifies the major stakeholders that can be affected by the given regulation and explains the process of consultation and communication with these stakeholders. This type of analysis sets up the major needs for reliable data and explains how the respective needs will be met.

In this section, it is recommended to consult the chapter on data collection and stakeholders’ consultation from this Manual.

E. Recommendations. Preliminary regulatory impact assessment recommends carrying out of some actions justified on the basis of item 8 criteria of RIA Methodology.

In this section, it is recommended to consult the chapter on impact analysis and comparison of options from this Manual.

F. Summary of the preliminary regulatory impact assessment and suggested decision/recommendation. Summary of the preliminary regulatory impact assessment shall be presented by the author of the draft regulatory act and shall contain the following:

- description of the process of consulting with the stakeholders;
- summary of alternative approaches;
- synthesis table of objections, comments and proposals provided in the process of preliminary regulatory impact assessment, including the ones forwarded by the Working Group of the State Commission on Entrepreneurial Activity;
- decision/recommendation to decline the development of a draft regulation without additional analysis or accept development of a new draft regulation without additional analysis, or to thoroughly study the urgency of the proposed draft according to the final regulatory impact assessment.

Final RIA document

Final regulatory impact assessment contains the following chapters:

A. Problem definition. Final regulatory impact assessment includes definition of the problem to be resolved and establishes the results that can be accomplished as a result of the regulation introduced by the state. Problem definition shall contain the following elements:

- legal element stipulating how the given problem is reported to a given public authority responsible for the state intervention;
- analytical element explaining what caused the occurrence of the given problem and estimating its magnitude;
- evaluation of possible consequences in case no actions are being undertaken;
- setting up the rationale for the state intervention.

While describing these elements, it is recommended to consult the chapter on problem definition and setting up objectives from this Manual.

B. Possible impacts, which include:

- benefits (all major positive impacts, including on areas of public health, national security and environment protection);
- costs (all major negative impacts, including social and economic costs);
- impact on small and medium enterprises (any negative or positive effects on the start-up and functioning of small and medium business enterprises);
- major distribution effects.

In this part, it is recommended to consult the chapter on impact analysis and comparison of options from this Manual.

C. Alternative options. Alternative options can be compared using the following summary table:

Alternative options	Benefits	Costs	Impact on Small and Medium Enterprises	Distribution problem	Uncertainties
Do Nothing					
Option 2					
Option 3					
Option 4					

In this part, it is recommended to consult the chapter on identification of options and impact analysis and comparison of options from this Manual.

D. Implementation. Final regulatory impact assessment suggests an enforcement strategy and estimates the following:

- financial cost of enforcement;

- current capacities of the public administrative authority responsible for the implementation of the regulatory act or other actions.

In this area, it is recommended to consult the implementation and monitoring chapter of this Manual.

E. Performance indicators. Final regulatory impact assessment identifies the specific and measurable indicators to monitor the deliverables linked directly with the goals identified in the state intervention. This section shall:

- recommend the indicators applied to estimate the efficiency of accomplished strategic results and of costs or other major negative impacts;
- present a monitoring strategy, including collection of data, consultation of core stakeholders and frequency of the monitoring.

In describing these elements, it is recommended to consult the implementation and monitoring chapter of this Manual.

F. Date of entering into force and validity term. Final regulatory impact assessment suggests and justifies, if the case be, the date when the proposed regulation shall become effective and substantiates the sunset term proposed for its implementation.

In drafting this part, it is recommended to consult the implementation and monitoring chapter of this Manual.

ANNEX 1. MAIN RIA QUALITATIVE CRITERIA GROUPED INTO KEY ELEMENTS

The main RIA qualitative criteria have been developed following the good international practices and, in particular, European Commission RIA Guide and OECD recommendations. These criteria serve the purpose of improving the analysis and the RIA document for those developing these assessments, as well as for the business community, RIA Secretariat and other institutions involved in revising and evaluating the quality of RIA document.

CRITERIA OF EVALUATING RIA QUALITY	DESCRIPTION OF CRITERIA
PROBLEM DEFINITION	
RIA shall include a clear evidence-based description of the nature of the problem and justify the proposed intervention	A problem represents an unsatisfactory situation. RIA shall explain why the situation represents a problem and why state intervention is needed. Market or regulatory failures serve as the main justification for the state intervention. In cases when the intervention is imposed by another regulation or the need for harmonization with EU legislation, it is recommended to additionally explain if the proposed intervention will contribute to solving certain problems.
RIA shall describe the existing policies/regulations affecting the problem	RIA shall analyze the interventions that have already been undertaken, as well as other already accepted and planned interventions that might have an effect on the analyzed problem. For instance, if it was decided that sanitary-veterinary authorization for the outlets specialized in trading with products of animal origin will be replaced with the registration of the given units, the given change shall be taken into account when developing new interventions. This will make it possible to avoid duplication and unjustified costs incurred by the business community and society at large. Or, it might happen that although a regulation has already been adopted to resolve the given problem, the unsatisfactory situation remains unchanged due to weak implementation/enforcement of the

	respective regulations. In this case, the solution might be to develop another implementation/enforcement procedure rather than developing a new regulation.
To the extent possible, the magnitude and scale of the problem shall be quantified. If quantification is not possible, the reason for that shall be properly explained. The principle of proportionality shall also be applied, which means that preliminary Regulatory Impact Assessment will require less quantification than the final RIA, or less important problems need a lower degree of quantification.	Quantification of the problem enables us to understand if the state intervention is justified when the scale of the problem is sufficiently large, as well as to estimate the depth of the analysis depending on the significance of the problem since bigger problems require a higher analytical effort. Moreover, this quantification allows establishing measurable objectives. Without quantification of the problem, it will be difficult to determine if the implemented solutions have helped addressing the given problem.
Problem causes shall be clearly identified.	It is important to understand the causes of the given problem and target the options towards them. If causes are not identified, intervention may be erroneously chosen and focused on symptoms (undesired situation) and after the implementation it can even worsen the situation.
Problem shall not be defined as lack of an action or regulation	Problem shall not be defined as “lack of actions” or “need to undertake an action”, since if that is the case the assessment will be more inclined towards one option only, which might not be the most reasonable or cost-efficient (cheapest) solution. Similarly, such stipulations as “lack of a regulation represents a problem” shall also be avoided since regulation is just one of the possible options (alternative solutions) to address the problem.
SETTING OBJECTIVES	
RIA shall set the main objectives related to the given problem and its causes	If the objectives are not clearly linked to the problem and its causes, the options identified to achieve the given objectives may be channeled into the wrong direction and their eventual implementation can even make the situation worse or create other problems.
Objectives shall not be set as the need to undertake an action or introduce a	Objectives shall not be set as “the need to undertake a certain action” because in that

regulation.	situation the analysis will be inclined to one option only, which might not be the most reasonable or cost-efficient (cheapest) solution. Similarly, such stipulations as “the need to develop a regulation” shall also be avoided since regulation is just one of the possible options (alternative solutions) to address the problem.
To the extent possible, objectives shall be measurable and time-bound. The principle of proportionality shall also be applied, which means that objectives set in the preliminary RIA can be less measurable and time-related in comparison with the final RIA, or issues of less importance will require less measurable and time-bound objectives.	Measurable and time-bound objectives enable to monitor the implementation of options and evaluate to what extent they produce the expected outcomes.
IDENTIFICATION OF OPTIONS	
RIA should include the “do nothing” option/ baseline scenario	“Do nothing” option is the baseline scenario, which explains how the current situation will evolve without any additional interventions of the state. It includes all interventions that are already in the process of implementation and the ones that have already been approved and planned. The given option allows understanding better if the intervention is necessary in case the situation evolves in an unsatisfactory manner, as well as serves as a basis for comparing alternative options.
The identified options shall be clearly related to the objectives and causes of the problem.	If the given options are not clearly linked to the objectives and causes of the problem, they can be channeled in the wrong direction and their implementation can even worsen the situation (problem) or create other problems.
RIA shall include the main realistic options, including non-regulatory options, such as information and education measures, self-regulation, voluntary practices, etc. If non-regulatory options are not included, the reason for that shall be clearly explained.	Non-regulatory options, such as information and education, self-regulation, and others can reduce the costs and increase the effectiveness of the state interventions. Therefore, it is important to consider all realistic options to resolve the given problem and reach the set-up objectives.

IMPACTS ANALYSIS	
Main costs and benefits shall be described for each option separately, including the economic, social and environmental ones, which shall be proved by evidence.	RIA shall include potential economic, social and environmental impacts both intended (which, as a rule, are the objectives) and unintended ones for each of the analyzed option. This enables us to make a comparison among all the options, as well as draw a comparison with the “do nothing” option (baseline scenario). If any of the options does not entail economic, social or environmental impacts, it shall be mentioned and explained.
Impacts shall be quantified to the extent possible. The proportionality principle shall be applied, which means that preliminary RIA requires less quantitative assessment than the final RIA, or less important impacts require less quantitative consideration.	The more quantified the impacts are, the more reliable and convincing is the assessment. In this case, decision makers have better possibilities to compare all the existing options and adopt a better/more qualitative decision, which is based on more evidence and information. Impacts can also be quantified in natural units; however, evaluation of the impacts in monetary terms represents a most advanced level of quantitative estimation. However, in some situations this type of evaluation is not possible, in particular, for social and environmental impacts. If impacts are not evaluated in quantitative units, the reason for that shall be explained as it is mentioned in the next criterion.
If impacts are not assessed in quantitative terms, they shall have some qualitative assessment.	If the impacts can not be measured in quantitative terms or if the given estimation is too difficult to be conducted due to lack of time, resources or relevant data or on the basis of the proportionality principle, this shall be explained. In this case, the impacts will be assessed from qualitative point of view to enable comparison of options and shall be accompanied by a specification saying, for instance, how many people will be affected, what categories of people are most likely to be affected by the given option, such as vulnerable groups, etc. For the purpose of comparing and evaluating such impacts, these effects can be

	characterized as “small”, “medium” or “big”.
RIA shall assess only additional costs and benefits as compared with the situation when no additional actions are undertaken, i.e. compared to the “do nothing” option.	In describing the impacts of the analyzed options, RIA shall evaluate such impacts as net changes against the “do nothing” option (baseline scenario), which are also called incremental or marginal costs and benefits (changes or deviations from the baseline scenario). RIA shall also show how each option is different from the baseline scenario through its impacts (benefits or costs).
RIA shall analyze separately, if necessary, some specific impacts (impacts over the fundamental rights of people, impacts on SME, competition, etc.).	Even if an option generates net benefits (total benefits outweighing total costs), it can nevertheless have disproportionate effects over some groups from the society or areas of the economy. Therefore, it is important to stipulate if such disproportionate effects are likely to occur and evaluate them if they are likely to be significant.
COMPARISON OF OPTIONS AND RECOMMENDATION OF OPTIONS	
RIA shall present a summary of both positive and negative economic, social and environmental impacts for the analyzed options.	The summary of all social, economic and environmental impacts for all the options are, as a rule, presented in form of a table. This allows making an easier comparison of all the options, which is beneficial in consultation with both stakeholders and decision makers.
Benefits of the proposed options shall justify their costs. These criteria might not be applicable in cases of approximation to EU legislation or other similar cases when some measures are required to be taken even when their costs outweigh the benefits. In this situation, the “do nothing” option appears unfeasible and can only be used as a baseline scenario for estimation of impacts.	RIA shall evaluate total costs and benefits and determine if the benefits justify the costs, i.e. if benefits are higher than costs. In cases of approximation to EU legislation, RIA can help identify the most cost-efficient option to implement the EU legislation. In such cases, the “do nothing” option is not a feasible scenario and it can only be used as a baseline scenario to estimate the value of impacts. A similar situation might appear in case of other commitments or international covenants.
The recommended option shall generate higher net benefits and be the most efficient method in achieving the objectives as compared with the other options. The proportionality principle shall also be applied, which means that the	RIA shall compare the benefits and costs of each option in order to determine the option which generates higher net benefits (difference between total benefits and total costs) and is the most efficient in achieving RIA objectives from the point of view of

preliminary RIA requires less quantitative assessment than the final RIA, or in other words, less important impacts require less quantification and hence options shall be compared on the basis of a more qualitative assessment of the given impacts.	costs (the most cost-effective option). The “do nothing” option is not feasible for cases of approximation to EU legislation and it can only be used as a baseline scenario to calculate the impacts. However, RIA can help identify the best/most cost-efficient (the cheapest) option to implement the given EU legislation.
RIA shall describe an implementation plan, including the deadline by which the regulations proposed for the recommended option will become effective.	RIA shall envisage an implementation plan providing more details about the recommended option and how it will be brought into action. This will help understand whether the option is realistic and ensure a better allocation of resources necessary for its implementation.
RIA shall describe how the proposed option will be monitored and evaluated once the implementation starts, including performance indicators used for this purpose.	RIA shall describe how the efficiency of the recommended option will be evaluated and monitored. This will help the authors understand if the estimations used in RIA have been calculated correctly and decide if no adjustments are needed in the process of implementing the recommended option.
DATA COLLECTION AND CONSULTATION	
RIA shall be based on evidence.	RIA document shall present information on the source of data used to make the analysis, which will make it more trustworthy and reliable.
All relevant ministries, state agencies and institutions shall be adequately consulted.	It is important to ensure a proper consultation through the RIA process with all relevant ministries and agencies, which can supply data and influence the analyzed option and area. Ministries may help carrying out a more qualitative analysis of fiscal, social, economic and environmental impacts. Moreover, some implementation agencies can provide important data about the degree of compliance and enforcement/implementation capacities of the given authorities.
External stakeholders, such as citizens, civil society, business community shall also be consulted at the necessary stages of RIA preparation and be given sufficient time for their feedback and participation.	Once stakeholders are identified, it is important to think about a consultation strategy since these stakeholders are engaged at different stages of RIA preparation, including problem definition, development

	of options and analysis of impacts. Moreover, different stakeholders require different consultation methods and time for their responses.
RIA shall record all responses collected during the consultation process and explain if the consultation outcomes have been then used.	It is important to record and present the consultation results in RIA document and explain how they have been used in the given analysis. This will enhance the quality of the RIA documents and will make it more credible.
RIA shall be published.	Final public consultation of the RIA document plays an important role. The document shall be placed for consultations on the official web page and sufficient time shall be provided for responses. It is recommended that public consultations shall last not less than 30 days.

ANNEX 2. EXAMPLE OF NET PRESENT VALUE CALCULATION (COST-BENEFIT ANALYSIS)

This example was taken from the RIA developed by the Ministry of Agriculture and Rural Affairs of Turkey in 2009 for the Regulation on establishment of an integrated administrative and control system and of a land parcel identification system in Turkey.

The systems proposed in the given Regulation are aimed to optimize the farmers support schemes.

Calculation of net benefits, million EUR

	2009	2010	2011	2012 ³	2013	2014	2015	2016	2017 ⁴
Discount rate ¹	2.5%								
Benefits ²	0	0	0	0	105.3	105.3	105.3	105.3	105.3
Present value of benefits	538.6	0	0	0	95.4	93.1	90.8	88.6	86.4
Costs									
- investment	0	0	0	12.5 ⁵	0	0	0	0	0
- operational	0	0	0	7.5	7.5	7.5	7.5	7.5	7.5
Present value of costs	50.0	0	0	11,6	6,8	6,6	6,5	6,3	6,2
Net present value (9 years) ⁶	488.6	0	0	-11.6	88.6	86.4	84.3	82.3	80.3

¹ – Discount rate is the rate applied by the Government for non-material (pecuniary) payments to farmers.

² – Benefits were calculated as reduction in money losses/leakage (subsidies paid to farmers that do not meet the requirements for their allocation) worth 8.1% of total subsidies that will be allocated through the implementation of the new system. The problem of this RIA is related to the high share of money losses/leakage, i.e. 8.1% of subsidies were collected by the farmers that did not enforce the legislation on good practices in agriculture mainly aimed at increasing environmental benefits. It was assumed that the new control system will help identifying such cases of incompliance and will contribute to proper enforcement of all the conditions by the farmers in order to be eligible for the given subsidies. Therefore, the real impact will represent the benefit for the environment estimated to, at least, be equal to the value of total subsidies allocated for the accomplishment of the given benefits.

³ – year of launching the new system.

⁴ – estimated year of Turkey's accession to EU, which is based on a supposition in order to limit the analysis period to 9 years.

⁵ – investments from the state budget for the creation of the given system. They do not include EU technical assistance funds since they do not represent real costs incurred by Turkey.

⁶ – Net present value is calculated on the basis of the following formula:

$$NPV = \sum_{t=0}^n \frac{Bt - Ct}{(1 + i)^t},$$

where Bt and Ct are costs and benefits from year t , i is the discount rate and n is the number of discounted years.